APPENDIX

INDEX TO APPENDICES

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
January 15, 2020
Lyle W. Cayce
Clerk

No. 18-41067

PALM VALLEY HEALTH CARE, INCORPORATED,

Plaintiff-Appellant

v.

ALEX M. AZAR II, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; PALMETTO GBA, L.L.C.,

Defendants-Appellees

Appeal from the United States District Court
for the Southern District of Texas

Before OWEN, Chief Judge, and HAYNES and COSTA, Circuit Judges.

GREGG COSTA, Circuit Judge:

With annual spending topping half a trillion dollars, Medicare is the largest recipient of federal funds after Social Security and defense.[1] With so many tax dollars at stake, Congress created an administrative process through which Medicare can recover overpayments. Because of the massive number of claims, an audit of each one is not feasible. So federal law allows Medicare to investigate a select number of claims from a provider. If the audit of that sample reveals "a sustained or high level of payment error," Medicare can

[1] Leigh Angres & Jorge Salazar, *The Federal Budget in 2018*, Congressional Budget Office (June 2019), https://www.cbo.gov/system/files/2019-06/55342-2018-budget.pdf.

extrapolate that overpayment rate to a larger number of similar claims. 42 U.S.C. § 1395ddd(f)(3)(A).

An audit of Palm Valley Health Care, a home health care provider, revealed that a significant percentage of the sampled claims did not meet Medicare coverage requirements. Extrapolating that overpayment rate to all claims paid over the relevant time period resulted in a repayment demand of more than $12 million. Palm Valley brings constitutional, statutory, and evidentiary challenges to that decision. Finding no error, we AFFIRM.

I.

The Department of Health and Human Services (HHS), acting through a Medicare contractor, audited claims Palm Valley submitted between July 1, 2006, and January 31, 2009. Palm Valley was selected for review because it had submitted an unusually large number of claims involving five or more consecutive home health care episodes. An episode is sixty days long and the typical claim involves two consecutive episodes. During the audit period, Palm Valley submitted 10,699 Medicare claims.

Out of those thousands, the contractor sampled 54 and concluded that 29 of them provided services to beneficiaries who were not eligible for home health care. Medicare will cover home health services if the beneficiary is homebound, under the care of a physician, in need of skilled services, and under a plan of care. 42 C.F.R. § 409.42. Based on interviews of beneficiaries and their friends and families, as well as a review of medical records, the contractor concluded that the 29 beneficiaries either were not homebound or did not need skilled care.[2] As a general matter, an individual is homebound if she has a condition restricting her ability to leave home without assistance. 42 U.S.C. § 1395f(a). The overpayment for those 29 claims was $81,681.03.

[2] Palm Valley does not appeal the agency's determinations that various beneficiaries did not need skilled care.

Extrapolation turned that figure into a total repayment demand of $12,589,185.

Palm Valley sought review of the overpayment finding. It argued that the beneficiaries qualified as homebound and thus were eligible for home health services. It also challenged the sample the auditor used and the extrapolation methodology used to reach the $12 million repayment figure. Notably, however, Palm Valley did not press a defense Medicare allows for a provider that "did not know, and could not reasonably have been expected to know" that it was receiving overpayments.[3] 42 U.S.C. § 1395pp(a)(2); *see also Caring Hearts Pers. Home Servs. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (Gorsuch, J.) (calling this "[a] sort of good faith affirmative defense").

For the arguments Palm Valley was asserting, it had many opportunities to make them. Administrative review of overpayment decisions has several stages. The first allows a provider to seek a redetermination from the auditor. 42 U.S.C. § 1395ff(a)(3)(A). The auditor must complete its redetermination within 60 days. *Id.* § 1395ff(a)(3)(C)(ii). If the redetermination is unfavorable, the provider may then seek reconsideration from a qualified independent contractor, which likewise has a 60-day deadline. *Id.* § 1395ff(c)(3)(B)(i), (c)(3)(C)(i). The next step is an appeal to an administrative law judge (ALJ), who holds a hearing and reviews the overpayment finding *de novo*. *See id.* § 1395ff(d)(1)(A). The ALJ must render a decision within 90 days. *Id.* An unfavorable ALJ decision may be appealed to the Medicare Appeals Council, which also faces a 90-day deadline. *Id.* § 1395ff(d)(2)(A). If the provider fails

[3] In response to questioning at oral argument about the overpayment scheme, the government noted the availability of this defense and Palm Valley's failure to raise it before the Appeals Council. That led Palm Valley to file a postargument motion for leave to file a supplemental brief on its interpretation of yet another statute (42 U.S.C. § 1395gg) that it did not invoke before the Appeals Council. That motion is denied.

at this fourth and final stage of administrative review, it may seek review in federal district court. *Id.* § 1395ff(b)(1)(A).

Although each stage of administrative review has a statutory deadline, HHS routinely fails to meet those dates. From start to finish, the average appeal takes about five years, far in excess of the statute's approximately one year. *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 344–45 (5th Cir. 2017). The statute recognizes that the agency may not meet the deadlines. If HHS fails to meet the review deadline at any stage, a provider may escalate its appeal and immediately jump to the next stage of review. 42 U.S.C. §§ 1395ff(c)(3)(C)(ii), (d)(3)(A)–(B).

Palm Valley appealed through the entire administrative process. At the redetermination stage, the contractor determined that one partial denial among the 29 was in error. At the reconsideration stage, the independent contractor found that Medicare did not cover the claims for 29 beneficiaries. The ALJ subsequently reviewed the overpayment determinations and concluded that 27 claims in the sample of 54 should not have been paid. The Medicare Appeals Council mostly affirmed the ALJ's decision, but concluded that the claims for two beneficiaries previously found to be uncovered were eligible claims. Full administrative review thus reduced the number of ineligible claims from 29 to 25, shaving a meaningful amount off the $12 million that Palm Valley originally owed.

Consistent with recent practice, the ALJ and Medicare Appeals Council issued their decisions roughly one-and-a-half years and three years after Palm Valley sought their review. Although HHS did not come close to meeting either 90-day deadline, Palm Valley did not escalate its appeal.

Palm Valley finally sought review in district court. The court affirmed the decision of the Medicare Appeals Council.

II.

Palm Valley argues that HHS violated due process by failing to meet the statutory deadlines at each stage of the administrative process. We have difficulty seeing how Palm Valley was denied due process.

Due process typically requires "some form of hearing . . . before an individual is finally deprived of a property interest." *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976). Palm Valley received a hearing before it had to give any money back to Medicare. Its argument is essentially that it had too many hearings—really too many appeals of a hearing—and that they took too long. It does not cite any Supreme Court or circuit level authority finding a due process violation for delays occurring during an administrative appeals process.[4] And violation of a statutory deadline does not automatically mean a lack of due process; the Constitution, not statutes, determine the minimum procedures that due process requires. *See Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538, 538–39, 542 (1985) (recognizing that state statute created a property interest but applying *Matthews*' balancing test to determine what level of process the Due Process Clause required).

Even assuming the possibility of a due process violation arising from prolonged appeals of a hearing, Palm Valley failed to take advantage of the statutory escalation procedure that would have allowed it to expedite the process. Nor did it seek a federal court injunction to try and prevent recoupment. *See Family Rehab., Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018). One problem with allowing this after-the-fact complaint about delay is that it lets the provider have it both ways. Palm Valley took advantage of every

[4] It relies on *American Hospital Association v. Burwell*, 812 F.3d 183 (D.C. Cir. 2016), but that case does not address due process. If anything, it shows that Medicare providers may have another option when facing violations of the statutory deadline: mandamus relief. *Id.* at 132–34.

opportunity it had to undo the overpayment finding, and it took some bites out of the apple with partial success on some appeals. Only now, after going through every appeal, does it challenge the delay. *Contrast id.* (involving provider that brought action in district court once recoupment began because it faced a three-year delay before an ALJ).

The timing of Palm Valley's due process challenge also means it cannot show the substantial prejudice that is necessary for a due process claim to succeed. *United States v. Lober*, 630 F.2d 335, 337–38 (5th Cir. 1980) (per curiam). Palm Valley does not brief any theory of substantial prejudice, and none is apparent from the record. The roughly four-year delay did not affect HHS's ability to evaluate Palm Valley's claims, as the evidence that the agency drew on at each stage existed when Palm Valley first requested redetermination. Nor did the delay cause financial harm to Palm Valley. During the slow appeals process, HHS was not engaging in recoupment, the process by which Medicare holds back payments on new claims to cover overpayment findings that are still being appealed and thus may be overturned. *Contrast Family Rehab.*, 886 F.3d at 503 (holding that a district court had subject matter jurisdiction to consider a due process claim that a plaintiff subject to recoupment brought). In other words, HHS did not seek to recover any overpayment until the end of the appeals process. And as we have noted, Palm Valley preferred repeated review—with each level providing a new opportunity to succeed—to expeditious resolution of its claims. That choice to pursue each level of review shows that Palm Valley saw some benefit from pursuing multiple appeals despite the known delay each phase caused. Palm Valley has not established substantial prejudice from the delay.

The district court correctly rejected the due process claim.

III.

Turning from the process of the agency review to its substance, we consider Palm Valley's argument that the ALJ and Medicare Appeals Council applied the wrong definition of "homebound." An individual is homebound if he or she "has a condition . . . that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device . . . or if the individual has a condition such that leaving his or her home is medically contraindicated." 42 U.S.C. § 1395f(a). The statute further explains that "[w]hile an individual does not have to be bedridden to be considered 'confined to his home,' the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual." *Id.* The ALJ and Medicare Appeals Council, citing the statute as well as Medicare Program Integrity Manuals, stated in their reviews that a homebound person must have a normal inability to leave home and leaving home must "require[] a considerable and taxing effort."

Palm Valley argues this was too demanding a standard. It argues that for an individual to qualify as homebound, the condition of the person "should"—but not *must*—"be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual." 42 U.S.C. § 1395f(a); *see also Caring Hearts*, 824 F.3d at 973 (recognizing that "should" indicates a normal inability to leave home without a taxing effort is a useful, but not dispositive, test for homebound status).[5] Under Palm Valley's reading of section 1395f(a), whether an individual actually left home is largely irrelevant, as the inquiry must turn on whether

[5] Palm Valley repeatedly analogizes this case to *Caring Hearts*, 824 F.3d at 970–71. It does not mention that *Caring Hearts* decided whether the section 1395pp good-faith defense, which Palm Valley did not assert, applied.

the beneficiary has a condition restricting his or her ability to leave home without assistance.

But Palm Valley raised this argument for the first time in the district court. A federal court reviewing an agency determination will not ordinarily consider arguments that a litigant could have raised before the agency but chose not to. *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 174–75 (5th Cir. 2012). HHS limits the Medicare Appeals Council's review to objections a represented party asserts challenging the ALJ's ruling. 42 C.F.R. § 405.1112(c). The regulation tells a party that it must inform the Appeals Council if it believes the ALJ's ruling "is inconsistent with a statute, regulation, CMS ruling, or other authority." *Id.* § 405.1112(b). That covers the "homebound" argument Palm Valley raises now but did not mention before the Appeals Council. To allow Palm Valley to litigate an issue in federal court that it did not present to the Appeals Council would inappropriately "bypass[]" the agency's internal requirement.[6] *Sims v. Apfel*, 530 U.S. 103, 108 (2000); *see also, e.g., Medwin Family Med. & Rehab., P.L.L.C. v. Burwell*, 2017 WL 685696, at *17 (Jan. 31, 2017 S.D. Tex. 2017) (declining to consider issues not raised before the Medicare Appeals Council). A failure to dispute the governing legal standard before the agency is especially problematic given that the issue permeates the review process. Raising the "must" versus "should" issue before

[6] When a court decides whether to impose an "issue-exhaustion requirement even in the absence of a statute or regulation," it considers how much the administrative proceeding resembles "normal adversarial litigation." *Sims v. Apfel*, 530 U.S. 103, 108–09 (2000). Because there is a regulation requiring parties to identify specific ALJ errors before the Appeals Council, *id.* at 108, we need not decide whether the Medicare overpayment appeals process is sufficiently adversarial to require exhaustion. *See, e.g., id.*; *Vermont Dept. of Pub. Serv. v. United States*, 684 F.3d 149, 157–58 (D.C. Cir. 2012) (applying exhaustion requirement, without assessing whether the administrative process qualified as "adversarial," because regulation required exhaustion in agency proceedings); *Wolfe v. Barnhart*, 446 F.3d 1096, 1103 n.5 (10th Cir. 2006) (summarizing *Sims* as recognizing that "exhaustion is generally required in review of adversarial administrative proceedings or where exhaustion is mandated by agency regulation").

the agency would have allowed it to determine whether there is any practical daylight between those standards on these facts, something that is far from apparent. While judicial review of agency decisions plays an important role in correcting agency errors, it does not allow an inefficient redo based on arguments never presented to the agency the first time around. Because Palm Valley failed to exhaust its challenge to the "homebound" standard, we cannot consider the question.

IV.

We next consider Palm Valley's argument that HHS lacked substantial evidence for its finding that 25 beneficiaries were not homebound. Substantial evidence[7] supports a finding that a patient is not homebound if "more than a mere scintilla" of evidence support the determination. *Salmond v. Berryhill*, 892 F.3d 812, 817 (5th Cir. 2018) (quotation omitted).

That low evidentiary bar was met. The main thrust of Palm Valley's evidentiary challenge is that the Medicare Appeals Council and ALJ relied too heavily on interviews of individuals (including the beneficiaries themselves), who indicated the beneficiaries were not homebound. That testimony was unreliable, Palm Valley argues, because a significant amount of time, sometimes several years, had passed between the claims and the interviews.

As a general matter, Palm Valley is right that memories often fade over time. Basic principles of our legal system, like statutes of limitations and the right to a speedy trial, reflect that view. But the fact that passage of time may be grounds for impeaching testimony does not render that testimony

---

[7] We apply the substantial evidence standard rather than the Administrative Procedures Act's arbitrary and capricious standard because the parties agree that the former applies. We thus do not resolve which applies. *Cf. Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261 (5th Cir. 2017) ("assum[ing] only for the sake of argument that the APA's arbitrary and capricious standard applie[d]" and noting that "it probably ma[de] no difference" which deferential standard applied on review of Medicare's refusal to designate a hospital as a "critical access hospital").

irrelevant. This is the difference evidence law recognizes between relevancy and probative value. *Compare* FED. R. EVID. 401 (evidence is relevant if it makes a fact *any* more or less probable), *with* FED. R. EVID. 403 (excluding evidence if its tendency to make a fact more or less likely is too small relative to the costs of presenting it to the jury). Passage of time goes to the latter, not the former. Because even dated firsthand or eyewitness testimony about a beneficiary's health makes it more or less likely that the beneficiary was homebound, the interviews were undoubtedly relevant. In terms of probative value, as with impeachment evidence generally, the factfinder decides how much the passage of time undermines the credibility of testimony, if at all. Many considerations—including the level of detail the witness provides, the number of times the witness observed the beneficiary, and whether there is corroboration in the form of other witnesses or documents—will impact the reliability of the testimony.

The Appeals Council considered these factors when evaluating the interviews as part of its claim-by-claim review of the homebound question. Take, for instance, beneficiary R.L. The Council's determination that R.L. was not homebound relied in part on an interview with R.L.'s daughter two years after the dates of service. R.L.'s daughter described how two years earlier R.L. was able to drive to the barbershop and to visit his daughters. Also consider beneficiary F.D. Interviews with F.D. and a staff member in the building where F.D. lived revealed that F.D. was alert and frequently traveled outside the home, without assistance, for activities like shopping and visiting friends. For both these claimants, contemporary records corroborated the testimony. Clinical records demonstrated that R.L.'s medication changes could be managed without skilled care at home and that his diagnoses were unlikely to leave him confined to home. And Palm Valley's records showed multiple days when it had sent someone to F.D.'s residence, but the patient was not home.

Palm Valley's critique of the interviews is unavailing given the deferential standard of review. The Appeals Council carefully evaluated the evidence on each claim in an 86-page opinion. Substantial evidence supports HHS's determination that many beneficiaries were not homebound.

V.

The agency finding we have just upheld—that 25 claims were not eligible for payment because the patients were not homebound—does not on its own cause Palm Valley much financial harm. But the extrapolation of that overpayment rate to Palm Valley's more than 10,000 claims does. It thus is not surprising that Palm Valley also challenges that statistical analysis.

As we noted at the outset, HHS may use statistical extrapolation to determine overpayment amounts when the Secretary determines that "there is a sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3)(A); *see also Maxmed*, 860 F.3d at 344–45. The threshold determination that there are "sustained or high levels of payment errors" is not reviewable. 42 U.S.C. § 1395ddd(f)(3).

Palm Valley thus challenges not whether it was appropriate to use sampling and extrapolation, but the statistical methods the agency uses when performing those tasks. It contends that the methodology does not pass muster under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), because it has not been peer reviewed or generally accepted in the relevant scientific community. *Daubert*, however, does not apply in agency proceedings. *See Nat'l Taxpayers Union v. U.S. Soc. Sec. Admin.*, 302 F. App'x. 115, 121 (3d Cir. 2008); *Bayliss v. Barnhart*, 427 F.3d 1211, 1218 n.4 (9th Cir. 2005); *Niam v. Ashcroft*, 354 F.3d 652, 660 (7th Cir. 2004). It interprets Federal Rule of Evidence 702, and the federal rules of evidence do not govern agencies. *Niam*, 354 F.3d at 660; *see also* 42 U.S.C. § 405(b)(1) (allowing evidence to be received in Social Security hearings "even though inadmissible under rules of evidence

to court procedure"). What is more, the procedural "gatekeeping" aspects of *Daubert*, aimed as they are at preventing the jury from being tainted by unreliable evidence, do not translate to agency proceedings for the same reason they do not fully translate to bench trials: in reaching a decision, a judge will only rely on evidence the judge deems reliable. *See Whitehouse Hotel Ltd. P'ship v. Comm'r*, 615 F.3d 321, 330 (5th Cir. 2010) (recognizing that we have "noted that the importance of the trial court's gatekeeper role is significantly diminished in bench trials . . . because, there being no jury, there is no risk of tainting the trial by exposing a jury to unreliable evidence" (citing *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000)). Whether a judge's reliability finding was correct will be tied up in the substantive review of the decision. That is why some courts recognize that the substantive aspect of *Daubert*, with its focus on reliability, is practically speaking already part of substantive review of agency decisions. *See Donahue v. Barnhart*, 279 F.3d 441 (7th Cir. 2002) (explaining that *Daubert*'s "idea that experts should use reliable methods . . . plays a role in the administrative process because every decision must be supported by substantial evidence").

In looking at the extrapolation from that substantive standpoint, we see no reversible error. The methodology that the agency employed resulted in a random sample of 54 of the 10,699 claims, the audit of which provided an unbiased estimate of the actual average overpayment for all 10,699 claims. *See* MEDICARE PROGRAM INTEGRITY MANUAL § 8.4.1.3. Palm Valley's own expert testified that the sample was a valid probability sample and that the agency applied the correct formulas to extrapolate an aggregate overpayment amount from that sample.

Palm Valley argues that the sample was too imprecise—or more simply, that the Medicare contractor did not use a large enough sample. But as the Medicare Appeals Council recognized, demanding a larger sample to

marginally increase the precision of an estimate "ignore[s] real world constraints imposed by conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines." The extrapolation methodology may be imperfect, but it is the product of a complex balance of interests. At a minimum, it constitutes substantial evidence in support of the agency's decision. *Cf. Maxmed*, 860 F.3d at 343 ("Congress clearly envisioned extrapolation in overpayment determinations involving home health agencies like [the plaintiff], and the Secretary's reliance on extrapolation as a tool was justified."). If anything, the extrapolation methodology is provider friendly. The extrapolation does not assume that the average overpayment in the random sample occurred for the universe of claims. Rather, the agency assumes that the average overpayment for all claims is equal to a number that there is a 90% chance is *smaller* than the actual overpayment. *See* MEDICARE PROGRAM INTEGRITY MANUAL § 8.4.5.1 (explaining that the agency uses the lower limit of a 90% confidence interval as its overpayment estimate). That means that there is a 90% probability that the amount that Palm Valley was overpaid is greater than the approximately $12 million that the contractor initially calculated. *See id.* ("[I]t yields a demand amount for recovery that is very likely less than the true amount of overpayment . . . ."); *see also* JAN KMENTA, ELEMENTS OF ECONOMETRICS 188–89 (2d ed. 1997) (demonstrating the properties of confidence intervals).

We see no error in the extrapolation.

* * *

The judgment is AFFIRMED.

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED

January 15, 2020

Lyle W. Cayce
Clerk

No. 18-41067

D.C. Docket No. 7:15-CV-331

PALM VALLEY HEALTH CARE, INCORPORATED,

Plaintiff - Appellant

v.

ALEX M. AZAR, II, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; PALMETTO GBA, L.L.C.,

Defendants - Appellees

Appeal from the United States District Court for the
Southern District of Texas

Before OWEN, Chief Judge, and HAYNES and COSTA, Circuit Judges.

J U D G M E N T

This cause was considered on the record on appeal and was argued by counsel.

It is ordered and adjudged that the judgment of the District Court is affirmed.

IT IS FURTHER ORDERED that appellant pay to appellees the costs on appeal to be taxed by the Clerk of this Court.

Certified as a true copy and issued as the mandate on Mar 09, 2020

Attest: Lyle W. Cayce
Clerk, U.S. Court of Appeals, Fifth Circuit

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

PALM VALLEY HEALTH CARE, INC.,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 7:15-CV-331
	§	
SYLVIA MATHEWS BURWELL, *et al*,	§	
	§	
Defendants.	§	

ORDER

Now before the Court are Plaintiff Palm Valley Health Care, Inc.'s ("Palm Valley") Amended Motion for Summary Judgment (Dkt. No. 47) and Defendants Eric. D. Hargan's, Acting Secretary of the Department of Health and Human Services ("Defendant HHS"), and Medicare Administrative Contractor Palmetto GBA, L.L.C.'s ("Defendant Palmetto") (collectively, the "Defendants") Cross-Motion for Summary Judgment and Response to Plaintiff's Amended Motion for Summary Judgment (Dkt. No. 48).

After considering the Motions, the responsive pleadings, (Dkt. Nos. 47-49), and the applicable law, the Court hereby **ORDERS** that Palm Valley's Motion for Summary Judgment (Dkt. No. 47) be **DENIED** and Defendants' Cross-Motion for Summary Judgment (Dkt. No. 48) be **GRANTED**.

I. JURISDICTION

A United States district court has jurisdiction to review a final decision of the Secretary of the Department of Health and Human Services pursuant to 42 U.S.C. § 405(g). An individual (or provider) may bring an action for judicial review of such a final decision and the Court may enter a judgment affirming, modifying, or reversing the decision, and review whether the

findings of the Secretary are supported by substantial evidence. *Id.* Because Palm Valley has exhausted its administrative remedies regarding the decision of the Secretary, the Court finds that it has jurisdiction to adjudicate this dispute.

II. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Palm Valley — a medical service provider certified to participate in Medicare — submits claims for coverage of the home health services it provides for qualifying individuals. (Dkt. No. 47, p. 3); *see also* 42 U.S.C. § 1395f; 42 C.F.R § 409.40, *et seq*. Palm Valley submitted claims for the home health services provided from July 1, 2006 through January 31, 2009, which Defendant Palmetto, a Medicare administrative contractor, initially paid. (Dkt. No. 48, p. 7). Later, however, Health Integrity L.L.C., the Zone Program Integrity Contractor ("ZPIC"), reopened Palm Valley's claims. *Id.* ZPIC allegedly chose Palm Valley for post-payment review based on "an unusually high number of claims involving five plus consecutive home health periods during a specified period." *Id.*

ZPIC reviewed 54 of Palm Valley's 10,699 claims from the mentioned time period and determined that a total of 29 claims should have been denied because the beneficiary was either not homebound or did not have a qualifying skilled need. (Dkt. No. 47, p. 3). Based on this sample, the ZPIC calculated an actual overpayment of $81,681.03. *Id.* Because Defendant HHS determined that 29 of the 54 claims should have been denied, Defendant HHS determined that the rate of error was 54%. (Dkt. No. 48, p. 7). Extrapolating this 54% error rate to the universe, based on the lower limit of the one-sided 90 percent confidence interval, Defendant HHS calculated a total overpayment of $12,589,185.00. *Id.* Defendant Palmetto formally notified Palm Valley of the $12,589,185.00 Medicare overpayment on March 19, 2010 and Palm Valley pursued an administrative appeal of the overpayment determination through the four-stage

administrative process. (Dkt. No. 47, p. 1). Ultimately, however, the Medicare Appeals Council (the "Council") upheld the Secretary's determination of overpayment and issued a final agency decision, after which Palm Valley sought judicial review from this Court. (Dkt. No. 48, p. 13).

Palm Valley moves for summary judgment claiming that the Council's decision "is arbitrary and capricious, contrary to constitutional right, in excess of statutory authority, without observance of procedure, and unsupported by substantial evidence." (Dkt. No. 47, pp. 2, 26). Defendant HHS, in turn, asks the Court to uphold the Council's decision and underscores that the scope of this Court's review is narrowly limited to (1) whether there is substantial evidence in the record to support the Council's decision, and (2) whether the Council applied the proper legal standards in reaching its decision. (Dkt. No. 48, p. 2). Defendant HHS contends that, because the Council issued a meticulous and well-reasoned decision supported by ample and substantial evidence under the applicable law, the Court should affirm the Council's decision as a matter of law. (Dkt. No. 1, Exh. 1 — ADMINISTRATIVE RECORD). The Court considers the parties' arguments below.

III. OVERVIEW OF THE APPLICABLE LAW

A. Summary Judgment Standard of Review

A district court must grant summary judgment when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *see also Rogers v. Bromac Title Servs., L.L.C.*, 755 F.3d 347, 350 (5th Cir. 2014) (Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."). A fact is material if it might affect the outcome of the lawsuit under the governing law and is genuinely in dispute only if a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby,*

Inc., 477 U.S. 242, 248 (1986). A party moving for summary judgment has the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings and materials in the record, if any, which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); FED. R. CIV. P. 56(a), (c).

Once the moving party carries its burden, the burden shifts to the nonmovant to go beyond the pleadings and provide specific facts showing the existence of a genuine issue for trial. *Celotex*, 477 U.S. at 324; FED. R. CIV. P. 56(c). In conducting its review of the summary judgment record, the court "may not make credibility determinations or weigh the evidence" and must resolve doubts and reasonable inferences regarding the facts in favor of the nonmoving party. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 255; *Dean v. City of Shreveport*, 438 F.3d 448, 454 (5th Cir. 2006). The nonmovant, however, cannot satisfy its burden with "conclusory allegations, speculation, and unsubstantiated assertions which are either entirely unsupported, or supported by a mere scintilla of evidence." *Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 229 (5th Cir. 2010); *see also Brown v. City of Houston*, 337 F.3d 539, 541 (5th Cir. 2003) ("Unsubstantiated assertions, improbable inferences, and unsupported speculation are not sufficient to defeat a motion for summary judgment.").

B. Judicial Review of an Administrative Decision

Palm Valley contends that the standard of review should be under the Administrative Procedure Act's 'arbitrary and capricious' standard.[1] However, Defendants argue that the appropriate standard is found at 42 U.S.C. § 405(g): "(1) whether the [Secretary] applied the proper legal standards; and (2) whether the [Secretary's] decision is supported by substantial

[1] The test under the Administrative Procedures Act is whether the Secretary's decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Maxmed Healthcare Inc. v. Price*, 860 F.3d 335, 340 (5th Cir. 2017) (citing 5 U.S.C. § 706(2)(A), (E)).

evidence on the record as a whole." *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). The Court of Appeals for the Fifth Circuit recently addressed the same debate between a medical services provider and CMS and "assume[d] only for the sake of argument that the APA's arbitrary and capricious standard applies." *Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261 (5th Cir. 2017). This assumption was adopted by the Fifth Circuit again in *Maxmed Healthcare Inc. v. Price*, reasoning that the application of either test "probably makes no difference." 860 F.3d 335, 340 (5th Cir. 2017). This Court will follow the lead of the Fifth Circuit and apply the standard promulgated by the APA.

The Fifth Circuit defined "substantial evidence" in this context to mean "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Steere Tank Lines, Inc. v. Interstate Commerce Comm'n*, 687 F.2d 104, 105 (5th Cir. 1982) (cleaned up). Substantial evidence is something more than a scintilla but less than a preponderance. *New Thoughts Finishing Co. v. Chilton*, 118 F.3d 1028, 1030 (5th Cir. 1997). Defendant HHS is an "agency" within the meaning of the APA scope of review and thus, Defendant HHS's factual findings are governed by the deferential APA standard. Defendant HHS's legal conclusions, however, are reviewed *de novo*. *Rain & Hail Ins. Service, Inc. v. Federal Crop Ins. Corp.*, 229 F.Supp.2d 710, 717 (S.D. Tex. 2002).

The Secretary of the Department of Health and Human Services is charged with the primary responsibility for interpreting the reimbursement provisions of the Medicare Act. *Girling Health Care v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996). Accordingly, this Court must give substantial deference to an agency's interpretation of its own regulations. *Id.*

IV. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Palm Valley filed the instant Amended Motion for Summary Judgment and

briefs five separate reasons that it believes should cause the Court to grant summary judgment in its favor. The Court will address each of these causes in the order in which they are presented.

A. Defendant HHS Did Not Err in Affirming the Denials of Sampled Medicare Claims.

Plaintiff first contends that Defendant HHS erred in affirming the denials of sampled Medicare claims because: (1) the denial decisions heavily relied on "interviews conducted by the Medicare contractor in assessing the functional abilities of beneficiaries"; (2) the wrong qualification test to determine homebound status was applied, leading to improper denials; and (3) the wrong qualification test to determine medical necessity was applied, also leading to improper denials.

i. Denials on the Basis of Interviews

Palm Valley claims that the determination of the Secretary unfairly relied on "biased" interviews conducted by the contractor to assess homebound and medical necessity statuses. (Dkt. No. 47, p. 10). Palm Valley states that the interviews were unfair because they were conducted after a significant amount of time had passed since the services had been rendered. *Id.* Palm Valley also states that the medical records prepared by registered nurses would be more reliable evidence to assess patients' statuses and should have been given more weight. *Id.* at 11. Lastly, Palm Valley states that the "government usurps the physician's role and medical judgment in determining that Palm Valley was not entitled to payment" due to their incorrect determinations of homebound and medical necessity status. *Id.*

There are two purposes of the investigation into Palm Valley's Medicare claims. First, after detecting unusual claims activity from a provider, a review is necessary to ensure that the provider is not overcharging the government by submitting false claims; and second, to ascertain the extent of any overpayment on already-paid claims. With that in mind, the Court sees no

reason to weigh the medical records of a provider under review any more strongly than an interview of the beneficiary for which the claim was made. In fact, one may doubt the legitimacy of the medical records as they may, given the nature of the investigation, reflect untrue representations of the current conditions of the patient. A natural defense to the possibility of unrepresentative medical records is to acquire direct evidence. In this case, the court concludes that reasonable minds would find that interviews and home visits to verify the accuracy of the claims filed on their behalf are legitimate methods to conduct such a review and, therefore, relevant evidence.

The Court agrees with Defendant HHS that the Council considered Palm Valley's argument that the interviews were unreliable. (Dkt. No. 48, p. 31). For example, the Council noted that Health Integrity investigators inquired as to the beneficiary's status during the dates of the service.[2] Additionally, the Council stated that family members were often present to corroborate the beneficiary's status during the dates of service.[3] In reaching its decision, the Council reviewed the administrative record for each beneficiary which "generally included individual claim folders from the initial certification period (start of care), the certification period immediately before the home health episode at issue, the home health episode at issue (dates of service), as well as an additional unmarked folder which contain[ed] various procedural and clinical documentation, including the Beneficiary Interview" (referred to as the "BI"). (A.R. at 35).

The Council did not rely solely on the BIs, but also on medical records, physician notes,

[2] *See, e.g.*, (A.R. at 39, observing that the highlighted instructions on interview form state: "NOTE: Questions should be asked in relation to the period of review.").
[3] *See, e.g.*, (A.R. at 55, interview of R.L.'s daughter; A.R. at 60, noting that son and daughter-in-law of R.M. agreed with responses to questions).

and corroborating witness statements.[4] For example, with regard to M.A., "the appellant's contentions…[were] the most extensive in the request for review" and the Council reviewed this folder, noting that two of M.A.'s home health certifications for the period April 21, 2006, through June 19, 2006, were neither signed nor dated by the attending physician. (A.R. at 36-37). The Council further noted that M.A.'s visit note reports for this period were "almost all computer generated" and "substantially similar." *Id.* at 37, 39. In addition, the Council detected similar problems with other certifications of home health services and visit notes for M.A. *Id.* at 38. For instance, one set of M.A.'s records contained "a handwritten signature of the ordering physician on the first page which [differed] from the physician's signature" on the other pages and "[differed] from the handwritten date next to the signature." *Id.* at 39.

With respect to M.B., the Council observed that M.B.'s own physical therapist noted that during the dates of service M.B. "was independent or required minimal assistance" and there was "nothing in the gait analysis which [indicated] that the beneficiary was unable to leave the home." (A.R. at 42). Although M.B.'s BI "[indicated] that the interviewers found that [M.B.] was not at home [at the time of the attempted interview] but was 'playing bingo' in a day care center," the Council only partially relied on this information in determining that M.B. was not homebound in light of the physical therapist's notes. *Id.*

Likewise, the Council referred to medical records detailing M.C.'s ability to ambulate to clinics several times without a device and his ability to "[exercise] on a recumbent bicycle, [do] static pushups, and [perform] wall slide and wall pulley therapeutic exercises with a total exercise time of approximately one hour each session" during the period he was considered homebound. (A.R. at 45-46). Further, the Council noted that F.M.2's Admission OASIS form,

[4] *See, e.g.*, (A.R. at 82, "the contractor interviewed both the 61-year-old beneficiary *and* her daughter") (emph. added).

dated four months before the dates of service, "[indicated] that the beneficiary lived alone, received the assistance of family and paid caregivers multiple times daily, her cardiovascular and respiratory systems were within normal limits, she transferred with minimal assistance or with the use of an assistive device, she could go shopping with assistance, and she was alert, oriented to person and place." *Id.* at 57. As a result, the Council considered that Palm Valley could not show that "it required a considerable and taxing effort for [F.M.2] to leave her home." *Id.* at 58.

Similarly, the Council noted that M.P.'s records indicated that M.P. "received [physical therapy] services, which included 15 minutes on a manual pedlar [sic] exerciser and ambulating more than 1,000 feet without an assistive device, but with stand-by assistance." (A.R. at 62). Documentation demonstrated that M.P. "was discharged from [physical therapy] ambulating 300 feet independently, and also independent with a home exercise program…approximately three months prior to the dates of service." *Id.* Thus, the Council only partially relied on M.P.'s BI—which states that M.P. had previously "left for Mexico, and the family did not know when he would return"—in determining M.P.'s homebound status. *Id.*

The BIs also make clear that interviewers focused on the dates of service even if the interview was conducted years later. For example, F.D.'s BI stated that "during the interview and *the dates of service*…[F.D.] was able to leave home without help to go to church, shopping, the grocery store, and to visit friends or relatives." (A.R. at 41) (emph. added). As a result, the Council held that "[w]hile the [interview] occurred significantly after the dates of service, the contemporaneous clinical documentation [indicated] that the beneficiary was ambulatory and able to participate in multiple exercises calling for balance and strength." *Id.* at 51.

Similarly, J.B.'s BI revealed that J.B "'visited Mexico' *during the dates of service*." *Id.* at 43-44 (emph. added). Further, the Council noted that R.L., who was homebound at the time of

the interview, specifically stated that he was not homebound during the dates of service—statements corroborated by his daughter.[5]

P.M.'s "BI [stated] that P.M. was not homebound during the dates of service *and* at the interview." (A.R. at 58) (emph. added). "The BI also [indicated] that [P.M.] left her home 3-4 times weekly to go out to eat and shopping and that she took an assisted living facility bus when doing so." *Id.* The interviewer noted that P.M. "lived in an assisted living facility apartment described as 'very neat' and 'clean,' [] filled out her own medicine box which the nurse checked each week, [] wore an adult diaper when taking the facility bus as a precaution, [] required no assistance toileting or transferring, and [] was able to bathe and dress herself." *Id.*

Similarly, R.M.'s BI "[stated] that [R.M.] was not homebound during the dates of service" and that the "interviewer specifically questioned [R.M.] about the period September 2008 through November 2008." (A.R. at 59). Upon questioning, R.M. replied that there was "nothing medically different than now" and that he currently "left home on average 3 times weekly, without assistance, to go out to eat, shop, and for medical care, and '[could] come and go as he [pleased].'" *Id.* at 60. R.M. also asserted that he "received his first walker two weeks ago, but '[did not] use'" it. *Id.* Further, R.M.'s "son and daughter-in-law were present at the interview and corroborated his responses." *Id.*

E.P.'s BI also "specifically [discussed] services provided at the time of the home health episode and [was] consistent with the ALJ's findings" because the BI stated that "'three years ago,' [E.P.] did not require help bathing, toileting, transferring or ambulating, but 'now uses a walker.'" (A.R. at 59). Palm Valley had complained that E.P.'s "BI was completed almost three

[5] *See* (A.R. at 55, describing that in response to the question "Are/Were you able to leave your home?" R.L. answered, "not now—2 years ago was able to drive [myself] around."); *see also* (A.R. at 55, R.L.'s daughter stating that "2 years ago [R.L.] was driving himself around—driving himself to the barber, he was able and did go by himself.").

years after the dates of service, and [that] clinical records [indicated] that [E.P.] was forgetful." *Id.* The interviewer, however, spoke to E.P.'s daughter who "had lived with [E.P.]...during the dates of service" and corroborated E.P.'s statements about his homebound status. *Id.* at 60.

Likewise, B.S.'s BI "specifically [addressed] the dates of service" and B.S. "stated that [his] condition was the same then as now, [and] he was not homebound." (A.R. at 70). B.S. stated that he "was able to leave home, did not require assistance in doing so, and...left home to go to church, the grocery store, shopping, and for medical care and...also went 'to the ranch on a regular basis.'" *Id.* Further, B.S.'s "wife also stated that they shopped at Wal-Mart" and that B.S. "drove himself around." *Id.*

M.S.2's "BI specifically [indicated] that [M.S.2] was not homebound during the dates of service, as well as at the time of the interview." (A.R. at 72). The interviewer noted that M.S.2 "walked into the other room to retrieve medical information" and stated that she was able to leave home "for the grocery store and medical care, and [that] her daughter drove her to medical appointments." *Id.* The Council, however, ultimately determined that M.S.2 was not homebound because "she had no cane, walker, or wheelchair" and thus there was "no taxing effort to leave home." *Id.*

Moreover, the Court does not consider the Council's attention to the beneficiaries' condition at the time of the interview an abuse of discretion because the record shows that the beneficiaries' current condition was helpful in determining the beneficiaries' homebound status during the dates of service. For example, although F.M.1 had been diagnosed with Alzheimer's and dementia, "the BI [contained] a handwritten notation indicating no Alzheimer's and no dementia, as stated by the beneficiary's wife." (A.R. at 55). The "BI [indicated] that [F.M.1] is 83 and "feels great!" *Id.* "The interviewer's observations also included that [F.M.1] was alert and

oriented, with comments 'very alert & able to answer all questions…wife present & she drives him everywhere.'" *Id.* Further, F.M.1's "activity level at the time of the interview was stated as "able to walk OK" but F.M.1's "wife assisted with bathing" although F.M.1 "needed no assistance transferring.'" *Id.* Because conditions such as Alzheimer's and dementia are degenerative, the Council considered it telling that F.M.1 was in good condition at the time of the interview almost two years later. *Id.* at 56. The Council used this information to make its determination and agreed with the ALJ that the BI indicated that F.M.1 was not homebound during the dates of service. *Id.* This finding is clearly supported by substantial evidence on the record.

Furthermore, the Council addressed whether certain beneficiaries would have qualified for skilled services even if the Council had already determined that the beneficiaries were not homebound. For example, the Council considered that J.R. was not homebound because J.R.'s BI focused on "the dates of service" and indicated that "[J.R.] reported knee pain during each nurse visit of level 2 intensity (on an undefined scale), which was relieved by rest and over the counter medication Tylenol 500 mg." (A.R. at 65). In addition, the Council also considered that J.R. was not homebound because he was absent from the home on at least three occasions prior to the dates of service. *Id.* Based on this information, the Council determined that Palm Valley had not shown that "it required a considerable and taxing effort to leave home." (A.R. at 65). Nonetheless, the Council briefed an analysis as to why J.R. also did not require the "skilled nursing services" Palm Valley provided. *Id.*

The Council underscored that "Medicare covers skilled nursing services for observation and assessment of a patient's changing condition when the skills of a nurse 'are required to identify and evaluate the patient's need for modification of treatment or for additional medical

procedures until his or her condition is stabilized.'" *Id.* (citing 42 C.F.R. § 409.33(a)(2)). The only documented ailments J.R. was suffering from, however, were an upper respiratory infection, requiring a blister pack to be taken over five days, and another ailment that required a prescription for a diuretic. (A.R. at 65). Regarding J.R.'s second claim for skilled services, the Council found that the record contained "no laboratory documents supporting" the "weekly B-12 injections" Palm Valley was administering. *Id.* at 68. Thus, the Council decided that J.R. did not require skilled services.

Similarly, the Council considered that other "homebound" beneficiaries did not require skilled care. For example, E.C.1 was living with "another family member" and received "assistance from relatives, friends, or neighbors living outside the home, a person residing in the home, and paid help." (A.R. at 47). As a result, the Council considered that one of those people should have been instructed on how to administer the necessary injections but found that Palm Valley made no attempt "to instruct the beneficiary, the paid caregiver, a family member, or anyone else to administer the daily [] injections during the dates of service or for approximately a year and a half before that." *Id.* Accordingly, the Council considered that Palm Valley did not meet its burden of proof of showing that the beneficiary required skilled services. *Id.*

The Council found the same for A.C. and noted that Palm Valley did not even challenge the ALJ's findings that "daily insulin injections did not constitute skilled care." (A.R. at 48). Moreover, the Council cited to the Medicare Benefits Manual in holding that Palm Valley failed to show why A.C. continued to require skilled nursing observation, management, and instruction services approximately two years after the start of care date. *Id.* at 49 (citing MEDICARE MANUAL, Ch. 7 § 40.1.2). Similarly, the Council took issue with the fact that even though E.C.2's physical therapist noted that E.C.2 had achieved maximum rehabilitation potential and

was discharged from physical therapy services, E.C.2 continued to receive skilled services. (A.R. at 50). As a result, the Council considered that these skilled services were not necessary and thus not covered under Medicare. *Id.*

In M.H.'s case, the Council noted that according to the Medicare Benefits Manual, M.H. "did not require or receive skilled services during the dates of service" because "the documentation [did] not support that [M.H. had] a medical condition that had stabilized or had 'reasonable potential'" for a "complication or further acute episode." (A.R. at 54) (citing MEDICARE MANUAL, Ch. 7, § 40.1.2). The Council also noted that the documentation did not "support skilled [physical therapy] services, as there [was] no expectation of material improvement with a reasonable and generally predictable period of time." (A.R. at 54). As a result, the Council found that that the ALJ properly denied M.H.'s claim.

Likewise, although the Council reversed the ALJ's "not homebound" determinations for beneficiaries A.S. and M.S.3, the Council considered that the services provided to A.S. and M.S.3 were not covered because the services did not meet skilled care requirements. (A.R. at 85). "Medicare covers skilled observation and assessment services, in part, when professional skills 'are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition *is stabilized.*'" (A.R. at 74) (citing 42 C.F.R. § 409.33(a)(2)). Because A.S.'s dates of service were "approximately two years after the start of care," the Council considered the condition changing and thus skilled nursing services were not required to identify and evaluate treatment options. (A.R. at 74). The Council also considered M.S.3's condition "changing" because the dates of service were approximately three and a half years after the start of care. *Id.* at 76. In addition, the Council found that skilled services were not required to instruct the beneficiary. *Id.* As a result, the Council determined that

the services were not covered.

The determination that a beneficiary is not homebound or did not utilize or need skilled nursing is a factual conclusion governed by the deferential APA standard. *See Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). After reviewing the administrative record and the Council's determinations for each individual claim, the Court concludes that Defendant HHS contemplated the factors for and against a "homebound" determination and articulated a "rational relationship between the facts found and the choice made." *See Delta Found., Inc.*, 303 F.3d at 563. The Council did the same in determining whether the beneficiaries required skilled care. As a result, the Court does not consider Defendant HHS's decision arbitrary and capricious under the deferential APA standard based on the Council's partial reliance on beneficiary interviews.

ii. Denials on the Basis of Incorrectly Applied Standards

Palm Valley asserts that from 2006 to 2009, "the Medicare manual merely stated that a person may be considered homebound if leaving the home requires considerable and taxing effort," which evidences the application of the newer, more onerous standard by the Council. (Dkt. No. 47, p. 12) (citing MEDICARE MANUAL, Ch. 7, § 30.1.1 (Rev. 1, Oct 1, 2003)). Palm Valley further contends that at the time of the services, absences from the home were acceptable, provided that they were infrequent, of short duration, or to receive medical treatment." *Id.* In addition, Palm Valley asserts that "the regulations back then seemed to ask whether a patient could leave home without [a supportive device]." *Id.* (citing *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 971 (10th Cir. 2016)).

With respect to the skilled nursing services Palm Valley supplied, Palm Valley stresses that when the disputed services were rendered, Defendant HHS's regulations were also far less

demanding, "requiring the provider to show merely that 'the patient's medical history may support the likelihood of a future complication or acute episode'" and that " the skilled nursing services provided were "reasonably expected to be appropriate treatment." *Id.* at 13-14 (citing MEDICARE MANUAL, Ch. 7, §§ 40.1.1-40.1.2.1 (Rev. 1, Oct. 2, 2003)).

The Court disagrees that the wrong standards were applied. Many of the Council's determinations explicitly contain the standard that Palm Valley argues the Council did not use—that "leaving the home [required] considerable and taxing effort."[6] (Dkt. No. 47, p. 13) (citing MEDICARE MANUAL, Ch. 7, § 30.1.1 (Rev. 1, Oct. 1, 2003)). It is clear, however, that the Council applied these regulations. For example, with regard to M.H., the Council stated that "the documentation [did] not support that [M.H. had] a medical condition that had stabilized or had 'reasonable potential'" for a "complication or further acute episode." (A.R. at 54). Further, the Council underscored that Palm Valley did not even challenge the ALJ's findings that "daily insulin injections did not constitute skilled care." *Id.* at 48. Indeed, Palm Valley points to no specific instance in which the Council applied "more *current* guidance for determining homebound status." (Dkt. No. 47, p. 12).

With respect to the denials for lack of medical necessity, the Court disagrees that the Council "based its denial of coverage for most patients for want of sufficient documentation". (Dkt. No. 47, p. 13). Instead, as discussed *supra*, the Council noted suspicious irregularities with the documentation, such as the fact that it was computer generated, substantially similar in

[6] *See, e.g.*, (A.R. at 35, rejecting that M.A. could leave the home "without considerable and taxing effort"; A.R. at 36, rejecting that Palm Valley "met its burden of proving that it required considerable and taxing effort for [M.C.] to leave the home during the dates of service"; A.R. at 56, agreeing with the ALJ that "the record did not support that leaving home required a considerable and taxing effort" for F.M.1; A.R. at 58, holding that Palm Valley did "not point to any specific information in the record to support that it required a considerable and taxing effort for [F.M.2] to leave her home"; A.R. at 65, holding that "the record does not support that it required a considerable and taxing effort to leave home" for J.R.; A.R. at 78, finding that the Council's review did not support that O.T. "had a 'normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort'"; A.R. at 80, holding that Palm Valley's contentions provide no basis for concluding that L.V. "had 'a normal inability to leave home, and consequently, leaving home would require a considerable and taxing effort'").

several cases, and sometimes seemingly signed by different persons on different pages. Further, the Council noted that the documentation was often at odds with beneficiary self-reports, family member reports, or with Medicare guidelines.[7]

As discussed *supra*, a reading of the administrative record shows that the Council reviewed all relevant factors in making its homebound and skilled nursing services need determinations. The Council did not rely solely on "isolated absences" or "want of sufficient documentation to justify medical necessity." (Dkt. No. 47, p. 13). Instead, the Council reviewed the individual claim folders pursuant to the Medicare statute and regulations, which "make clear that it is the responsibility of the provider or supplier [Palm Valley] to furnish sufficient information to determine whether payment is due and the amount of the payment." 42 U.S.C. § 1833(e); 42 C.F.R. § 424.5(a)(6). The Council then considered several factors with regard to each beneficiary and claim, as outlined in its extensive 50-page decision. (A.R. 34-85).

In sum, the Council clearly applied the proper skilled nursing care standards and found that some of the beneficiaries' medical histories did not support the likelihood of future complication or acute episode, and that certain skilled nursing services provided were not appropriate treatment. Accordingly, the Court does not find a clear error of judgment that would render the Council's decision arbitrary and capricious. *See Delta Found., Inc.*, 303 F.3d at 563. Thus, the Court affirms the Council's determination that the individual claims in the sample were properly denied.

B. Defendant HHS Did Not Err in Utilizing Statistical Sampling to Calculate the Extrapolated Overpayment.

Palm Valley challenges the validity of the sampling methodology used by Health Integrity to extrapolate the overpayment amount from the denied claims. This challenge states

[7] *See, e.g.* (A.R. at 50, observing that E.C.2's physical therapist noted that E.C.2 had achieved maximum rehabilitation potential and was discharged from physical therapy yet E.C.2 continued to receive skilled services).

that the extrapolation of the overpayment was improperly based on "mock statistics," was produced by an unqualified expert, and the methods employed were "not based in science."

Medicare contractors must follow six steps in conducting a statistical sample for overpayment estimation: (1) select the provider or supplier; (2) select the period to be reviewed; (3) define the universe, sampling unit, and sampling frame; (4) design the sampling plan and select a sample; (5) review each of the sampling units and determine if there was an overpayment or an underpayment; and (6) estimate the overpayment, if necessary. MEDICARE MANUAL, Ch. 7 § 8.4.1.3. "Extrapolation is one permissible method of calculating overpayments. In particular, Congress authorized Medicare contractors to 'use extrapolation to determine overpayment amounts' if the Secretary determines that 'there is a sustained or high level of payment error.'" *Maxmed Healthcare Inc.*, 860 F.3d at 337 (citing 42 U.S.C. § 1395ddd(f)(3)(A)).

CMS Ruling 86-1 provides that sampling for extrapolation purposes "only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." "Following an overpayment determination based on extrapolation, the burden shifts to the Medicare provider, who 'could attack the statistical validity of the sample, or [] could challenge the correctness of the determination in specific cases identified by the sample[.]'" *Id.*

As noted by both parties, the MPIM makes clear that a contractor's failure "to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." MEDICARE MANUAL, Ch. 7 § 8.4.1.1. Instead, "[a]n appeal challenging the validity of the sampling methodology *must* be predicated on the actual statistical validity of the sample as drawn and conducted." *Id.* (emph. added).

Here, Palm Valley asserts that the extrapolation is invalid because the rules accommodate for real-world economic constraints by using probability sampling. However, Palm Valley does not contend that Health Integrity failed to follow the 6-step guideline for sampling and extrapolation, nor does it challenge the validity of the actual statistical sample. Instead, Palm Valley attempts to disqualify the statistician that performed the statistical analysis, rendering her calculations meaningless. Palm Valley characterizes the statistician, Dr. Pu, as an "expert" and proposes that the Court ought to apply the *Daubert* standard for expert opinion testimony to her work. The Court declines to reach the issue of whether Dr. Pu's analysis should be subjected to a *Daubert* standard.

Here, the methodology to be employed in conducting an extrapolation from the sample is defined by CMS regulations and the issue is only whether this method was followed. There is no dispute about whether it was. In addressing these contentions, the Council had the following response:

> Suffice it to say, however, that given provisions in the MPIM and CMS Ruling 86-1, the fact that the ZPIC selected a sampling methodology size that another statistician may not prefer, or which may not result in the most precise point estimate, provides no basis for invalidating the sampling or the extrapolation as drawn and conducted in this case…The Council must give substantial deference to CMS guidelines, including where, as here, CMS chose a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts.

(A.R. at 30). This approach has been treated favorably by federal courts tasked with reviewing Medicare overpayment decision challenges, as this court is today. *See generally Maxmed Healthcare Inc.*, 860 F.3d at 342.

The Council determined that Palm Valley's challenge to the validity of the sample was without merit because it "failed to take into account all of the other factors that are involved in

the sample design." *Id.* at 53-54 (citing MEDICARE MANUAL, Ch. 3, § 3.10.4.3). Moreover, the Council emphasized that Palm Valley's burden was to show that the contractor had not complied with medical requirements for statistical sampling, and not to show that a larger sample size would have been better. (A.R. at 53-54). The Council asserted that "the perceived shortcomings in the ZPIC's methodology as identified by [Palm Valley's] statistical experts, [does] not demonstrate that the sampling and extrapolation were invalid." (A.R. at 25).

In reaching this conclusion, the Council noted that Palm Valley's statistical expert, "Dr. C," "had no argument with the ZPIC's selection of [Palm Valley] for claim review…that he agreed with the ZPIC's statistician that the formulas used were found in standard textbooks on statistical sampling, were implemented with the RATS-STATS software program, and were 'statistically valid.'" *Id.* at 26. The Council also acknowledged that Dr. C testified that "the primary problem in this case was the 'tiny sample' and that the contractor 'could have' chosen a different sampling unit, although it was not required." *Id.* The Council, however, felt that a difference in opinion was not sufficient to overturn the overpayment determination because it was obtained using Medicare's provider-friendly procedures.

Palm Valley also challenges the validity of the sample by stating that a sample not drawn from a universe that includes negative or underpaid claims is biased and not representative of the universe of claims, rendering the projected overpayment as inaccurate. Palm Valley argues that the MPIM requires the inclusion of negative and underpaid claims in the universe. (Dkt. No. 47, p. 21) ("Clearly, the Council's opinion is in direct contravention of MPIM § 3.10.5.2 (negative overpayments shall be used in calculating the estimated overpayment)."). This is not correct. The MPIM allows the contractor to define the universe as it sees fit, so long as the defined

universe leads to a valid statistical result.[8] As noted by Defendants, the rule cited by Palm Valley in support of this argument "refers to underpayments that may have been determined in the review of the sampling units as it relates to the calculation of the estimated overpayment amount; it does not apply to defining the sampling units or the universe." (Dkt. No. 48, p. 21, n. 15). This Court agrees and finds that the Council did not err in upholding the validity of the statistical sample. Offering 'better' statistical analyses will not suffice to invalidate a sample if the sample meets the regulatory requirements.

C. Defendant HHS Did Not Violated Plaintiff's Due Process Rights in Adjudicating the Administrative Appeal.

Palm Valley asserts that Defendant HHS violated its Due Process rights in adjudicating this appeal. (Dkt. No. 47, p. 8). First, Palm Valley contends that Defendant HHS violated its Due Process rights because crucial sampling documentation was withheld during the first two stages of the administrative process. *Id.* at 21. In a similar case, however, the Fifth Circuit held that it was "unaware of any authority holding that the agency processes become fundamentally unfair under the circumstances" described. *See Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 344 (5th Cir. 2017) (holding that due process was not violated when the contractor withheld "critical evidence such as the statistical sampling and extrapolation data and information" from the provider "'for years and through two appeal stages' (presumably referring to the redetermination and reconsideration stages)"). The Fifth Circuit considered it sufficient that the provider received the documentation "at least shortly before the ALJ hearing"—as is the case here. *Id.* Thus, Palm Valley's argument that "making this critical evidence available on the eve of the ALJ hearing does not cure the Due Process violation" fails. (Dkt. No. 47, p. 23).

[8] *See John Balko & Associates v. Sebelius*, 12-cv-0572, 2012 WL 6738248, at *12 (W.D. Pa. Dec. 28, 2012), *aff'd sub nom. John Balko & Associates v. Sec. U.S. Dept. of Health and Human Servs.*, 555 Fed. App'x 188 (3d Cir. 2014) (unpublished) ("the [Council's] decision that the exclusion of zero dollar payments was permissible, is supported by substantial evidence.").

Second, Palm Valley asserts that "the long delay in adjudicating the administrative appeal is so egregious as to violate Due Process." *Id.* Defendant HHS, however, asserts that Congress did not intend to create a due process claim for the Secretary's failure to abide by statutorily imposed deadlines, but instead provided a remedy in 42 U.S.C. § 1395ff(d)(3) in which the healthcare provider can bypass each step in the administrative process and escalate the claim to the next level—ultimately allowing the provider to reach judicial review within a relatively prompt time. (Dkt. No. 48, p. 37) (citing *Cumberland Cnty. Hosp. System, Inc. v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016)). The Court agrees with Defendant HHS's interpretation of section 1395ff(d)(3), titled "Consequences of failure to meet deadlines" which enumerates remedies other than a due process claim for providers, such as the bypass mechanisms.

Further, the Fifth Circuit addressed pressing concerns surrounding the backlog of Medicare appeals but conceded that "due process" cannot meticulously be observed under the present circumstances. *Maxmed Healthcare, Inc.*, 860 F.3d at 344. Just as Palm Valley highlights, in *American Hospital Association v. Burwell*, 812 F.3d 183 (D.C. Cir. 2016), a district judge issued mandamus relief "ordering the Secretary to resolve the backlog by 2020 and adjudicate [Medicare] appeals within statutorily imposed deadlines." In the status reports following the ruling, however, the Secretary indicated that the "backlog is increasing and not decreasing," and thus the Secretary "has no means to, and therefore cannot, meet the reduction targets…and simultaneously comply with the statutory requirements for appropriate payment of claims." *Maxmed Healthcare, Inc.*, 860 F.3d at 344. Accordingly, the Secretary "awaits resources and funding from Congress to remedy the problem." *Id.*

Thus, although the *American Hospital Association* court recognized that such delays were harmful to providers, the Court disagrees that Palm Valley's Due Process rights have "clearly"

been violated. (Dkt. No. 47, p. 24). Instead, the Court must agree with Defendant HHS that Palm Valley "cannot establish a due process claim when it cannot show an absolute right to a hearing [within] a certain period of time and failed to take advantage of the alternative remedy available under the statute." (Dkt. No. 48, p. 37). As a result, the Court holds that Palm Valley's due process claim fails as a matter of law. *Cf. Painter v. Shalala*, 97 F.3d 1351, 1357 (1996) (holding that a procedural due process claim requires that a plaintiff demonstrate a property or liberty interest in the benefit for which protection is sought).

D. Plaintiff is "Without Fault" and Not Liable for the Medicare Overpayment.

Lastly, Palm Valley contends that that Defendant Palmetto, the Medicare contractor, should be liable to Palm Valley for any amount that exceeds actual overpayment because of its alleged withholding of sampling documentation essential to challenging the extrapolated overpayment. (Dkt. No. 47, p. 26) (citing 42 U.S.C. § 1320c-6(b)). Defendant HHS, however, points out that section 1320c-6(b) applies to peer review organizations, which is wholly inapplicable to this case. (Dkt. No. 48, p. 38). The Court agrees with Defendant HHS that the "part" referenced in section 1320c-6(b) refers to part B of subchapter XI of Chapter 7 of Title 42, entitled "Peer Review of Utilization and Quality of Health Care Service." *Id.* at 39 (citing 42 U.S.C. § 1320c *et seq.*). Thus, the Court considers that Palm Valley's claim for damages against Defendant Palmetto fails as a matter of law because Palm Valley has not shown that Defendant Palmetto is a peer review quality improvement organization "or has a relationship with or furnishes to service such organization, within the meaning of § 1320c-6(b)."

V. CONCLUSION

Plaintiff Palm Valley has failed to demonstrate that the Council's decision to affirm the determination of an overpayment of $12,589,185 was erroneous. When tasked with challenging

the validity of the actual statistical sample, Palm Valley could not produce any evidence to support its position of invalidity. As discussed above, suggesting a 'better' alternative statistical analysis will not invalidate the original calculation if it comports with the rules and regulations promulgated by the Secretary of Health and Human Services. The Court finds that Palm Valley failed to meet its burden to show that the Council's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. The Court also finds that Palm Valley failed to show that it is entitled to summary judgment.

Because Defendant HHS withstands Palm Valley's attacks on its final agency decision as a matter of law, the Court holds that the Council's decision should be affirmed as a matter of law and Palm Valley should be held liable for the Medicare overpayment.

Accordingly, the Court hereby **ORDERS** that Plaintiff's Motion for Summary Judgment be **DENIED** and that Defendants' Cross-Motion for Summary Judgment be **GRANTED**.

SO ORDERED this 28th day of September, 2018, at McAllen, Texas.

Randy Crane
United States District Judge

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

PALM VALLEY HEALTH CARE, INC.,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 7:15-CV-331
	§	
SYLVIA MATHEWS BURWELL, *et al*,	§	
	§	
Defendants.	§	

JUDGMENT

In accordance with this Court's order denying Plaintiff's Amended Motion for Summary Judgment and granting Defendants' Cross Motion for Summary Judgment, the Court hereby ORDERS that Plaintiffs take nothing by this suit and the decision of the Medicare Appeals Council is affirmed in all respects.

SO ORDERED this 28th day of September, 2018, at McAllen, Texas.

Randy Crane
United States District Judge

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Departmental Appeals Board, MS 6127
Medicare Appeals Council
330 Independence Avenue
Cohen Building, Room G-644
Washington, DC 20201
(202)565-0100/Toll Free:1-866-365-8204

JUN 5 2015

ALJ Appeal Number: 1-716318652
Docket Number: M-12-3079

Palm Valley Health Care, Inc.
119 E. Canton
Edinburg, TX 78539
Attn: Alex Flores

NOTICE OF DECISION OF MEDICARE APPEALS COUNCIL

What This Notice Means

Enclosed is a copy of the decision of the Medicare Appeals Council (Council). If you have any questions, you may contact the Centers for Medicare & Medicaid Services (CMS) regional office or the local Medicare contractor.

Your Right to Court Review

If you desire court review of the Council's decision and the amount in controversy is $1,460 or more, you may commence a civil action by filing a complaint in the United States District Court for the judicial district in which you reside or have your principal place of business. *See* § 1869(b) of the Social Security Act, 42 U.S.C. § 1395ff(b). The complaint must be filed within sixty days after the date this letter is received. 42 C.F.R. § 405.1130. It will be presumed that this letter is received within five days after the date shown above unless a reasonable showing to the contrary is made. 42 C.F.R. § 405.1136(c)(2).

If you cannot file your complaint within sixty days, you may ask the Council to extend the time in which you may begin a civil action. However, the Council will only extend the time if you provide a good reason for not meeting the deadline. Your reason

must be set forth clearly in your request. 42 C.F.R. § 405.1134.

If a civil action is commenced, the complaint should name the Secretary of Health and Human Services as the defendant and should include the Docket Number and ALJ Appeal Number shown at the top of this notice. 42 C.F.R. § 405.1136(d). The Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States. *See* rules 4(c) and (i) of the Federal Rules of Civil Procedure and 45 C.F.R. § 4.1.

Enclosure

cc: Radhika Vemula, Esq.
Health Integrity
Chase Consulting
Q2A AdQIC Records Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-3079

In the case of	**Claim for**
Palm Valley Health Care, Inc. (Appellant)	Hospital Insurance Benefits (Part A)
M.A. and 26 others (see attached) (Beneficiary)	Multiple (see attached) (HIC Number)
Health Integrity, LLC (ZPIC) (Contractor)	1-716318652 (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a partially favorable decision, dated June 8, 2012, which concerned an extrapolated overpayment derived by statistical sampling of home health services provided to multiple beneficiaries. After reviewing a sample of 54 claims, the ALJ made favorable or partially favorable coverage determinations on 27 claims, and made unfavorable coverage determinations on the remaining 27 claims. The ALJ further found the appellant liable for the non-covered charges and the overpayment under sections 1879 and 1870 of the Social Security Act (Act). The ALJ also affirmed the statistical sampling and extrapolation methodologies as valid. The appellant has asked the Medicare Appeals Council (Council) to review the ALJ's decision, including the partially favorable and unfavorable coverage determinations for the 27 beneficiaries listed on the attachment. The Council admits the request for review and subsequent interim correspondence into the administrative record as Exhibits (Exhs.) MAC-1 through MAC-3.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). As set forth below, the Council affirms the ALJ's determination that the statistical sample and extrapolation methodologies in this case are valid. The Council also reviews the claim for each beneficiary appealed and makes

coverage determinations, as set forth below. The Council affirms the ALJ's finding that the appellant is liable for the non-covered services and extrapolated overpayment under sections 1879 and 1870 of the Social Security Act (Act).

BACKGROUND

The appellant provided various home health services to multiple beneficiaries for dates of service July 1, 2006, through January 31, 2009, and the appellant submitted claims to the Medicare Part A contractor. Dec. at 1. The contractor paid the claims initially, and the Zone Program Integrity Contractor (ZPIC), Health Integrity, LLC, later reopened the claims for post-payment review. *Id.* The ZPIC conducted a statistical sample of claims and extrapolated an overpayment of $12,589,185.00 to the universe of claims. *Id.* at 1-2. The contractor generally upheld the overpayments in individual redeterminations, with one partially favorable redetermination. *Id.* at 2. On October 14, 2010, the Qualified Independent Contractor (QIC) issued an unfavorable reconsideration, finding that services provided to 29 beneficiaries were not covered and upholding the statistical sample and extrapolation. *Id., citing* Exh. 4, at 28-94.

ALJ Hearing and Decision

On December 11, 2010, the appellant requested an ALJ hearing and enclosed an accompanying brief. Dec. at 2, *citing* Exh. 4, at 1-21. On December 13, 2011, the ALJ issued a Notice of Hearing, which, in relevant part, stated the issue as follows: "Any part of the decision you are appealing may be reviewed, including parts which you agree with. ***When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used by the QIC, in accordance with 42 C.F.R. § 405.1064.***" Exh. 9, at 2 (bold and italics in original). The ALJ conducted a pre-hearing conference on March 7, 2012; issued a "Pre-Hearing Conference Order," dated March 9, 2012, which scheduled the telephone hearing for April 10, 2012; and issued an Amended Notice of Hearing, scheduling the telephone hearing for April 10, 2012, and April 11-13, 2012, if needed. Exhs. 13; 18, at 1-3; 21, at 1-6.

The ALJ conducted the telephone hearing from April 10, 2012, through April 11, 2012, at which the appellant was represented by counsel and presented multiple witnesses, including

statistical sampling experts Dr. G.C. and Dr. J.W. Dec. at 2-3. The Council has audited the relevant portions of the hearing recording. The ZPIC appeared at the hearing as a non-party participant, through its representative Chase Consulting, LLC, and presented witnesses that included ZPIC statistician H.P. *Id.* at 3. The appellant's statistical experts filed a "Preliminary Report," dated March 5, 2012, and a post-hearing "Supplementary Report by Barraclough LLC," dated April 17, 2012. Exhs. 24, at 1-13; 30, at 48-55. The ZPIC's statistical expert, H.P., filed the "Expert Opinion on Health Integrity, LLC's Investigation of Palm Valley Health Care, Inc. and Resultant Issues set forth in ALJ Appeal Number: 1-716318652," dated April 6, 2012. Exh. 28. These documents set forth the opinions of the statistical experts, and the bases for those opinions, and are consistent with hearing testimony.

On June 8, 2012, the ALJ issued a partially favorable decision (171 pages). The ALJ made detailed coverage reviews of individual claims for 53 beneficiaries, finding that the sampled services for 26 beneficiaries (the sample included two separate claims for Beneficiary J.R.) were not reasonable and necessary and were not covered under Medicare Part A. Dec. at 47-49, 55-171 (Decision Addendum). The ALJ also found the appellant liable for the non-covered charges and not entitled to waiver of overpayment under sections 1879 and 1870 of the Act. *Id.* at 49-50. The ALJ upheld the validity of the statistical sampling and extrapolation and the extrapolated overpayment amount. *Id.* at 50-53.

Request for Review

On August 9, 2012, the appellant filed with the Council a request review of the ALJ's decision (55 pages). Exh. MAC-1. Under "Errors of Law," the appellant argues that the ALJ erred on the following issues:

- Violation of the "No Rule of Thumb" Mandate (*Id.* at 3-4)
- Limitation on Use of Extrapolation (*Id.* at 4-6)
- Application of 42 C.F.R. § 405.1064 (*Id.* at 6-7)
- Recoupment of overpayment during appeals (*Id.* at 7-8)

Id. at 3-8. Under "Errors of Fact," the appellant argues that the ALJ erred on the following issues:

- Conducting *de novo* review of sampled claims for 27 beneficiaries (*Id.* at 8-43)
- Not considering the "substantial evidence" of the expert opinion of the appellant's statistical sampling experts (*Id.* at 44)
- Accepting ZPIC statistical sampling methodology as valid (*Id.* at 44-54)
  - Not applying Medicare Program Integrity Manual (MPIM)(Pub. 100-08) Ch. 3, § 3.10.2 (*Id.* at 44-46)
  - Not applying Supreme Court *Daubert* test for scientific evidence and expert opinion (*Id.* at 46-48)
  - Ignoring "multiple tests" by appellant's statistical experts that the sample was not representative of the universe (*Id.* at 48-50)
  - Being "too liberal and providing undue leeway and flexibility to the accuracy and procedural correctness used by the Contractor" (*Id.* at 51-54)

The appellant asserts that all sampled home health services are covered by Medicare because the sampled beneficiaries were both homebound and required skilled services. *Id.* at 54. The appellant also asserts that "the extrapolation" of the overpayment should "be eliminated" because the contractor failed to "properly execute" the statistical sample, resulting in an invalid statistical sample. *Id.* at 54-55.

APPLICABLE LEGAL AUTHORITIES

Extrapolation of Overpayments

The Medicare Integrity Program provides as follows for extrapolation of a sample overpayment to the universe of claims:

> A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise *unless* the Secretary determines that -
> (A) there is a sustained or high level of payment error; *or*
> (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

Section 1893(f)(3) of the Act (emphasis supplied); 42 C.F.R. § 405.926(p).

Statistical Sampling

CMS (formerly the Health Care Financing Administration or HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. The Ruling provides, in pertinent part:

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1-9, 86-1-10.

CMS's sampling guidelines in effect at the time of the sample are found in Chapter 3 of the MPIM (Pub. 100-08). *See* MPIM Ch. 3, § 3.10 (eff. 05-10-04, *now* at MPIM Ch. 8, eff. 06-28-11). (CMS manuals can be found at http://www.cms.hhs.gov/manuals. Because the sampling guidelines were located in chapter 3 of the MPIM at the time the sampling at issue was conducted, the Council cites to the provisions in chapter 3 rather than to their newer chapter 8 locations.)

The MPIM guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample

sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the contractors to assess the overpayment at the lower level of a confidence interval--generally, the lower level of a ninety percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides contractors guidance in conducting statistical sampling for such overpayment estimations. These instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments when claims review indicates that overpayments have been made. The MPIM describes this purpose as follows:

> These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the [ZPIC] or the Medicare [Benefit Integrity] unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. *An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC or Medicare contractor [Benefit Integrity] unit or the contractor MR units to follow one or more requirements* may result in review by CMS of their performance, but *should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.*

MPIM Ch. 3, § 3.10.1.1 (emphasis supplied).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample," stating as follows:

> [The contractor] shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling the following two features must apply:
>
> - It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large---possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
> - Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.
>
> For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. *If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that*

> *the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always 'valid.' Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods.* A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

MPIM Ch. 3, § 3.10.2 (emphasis supplied). The MPIM recognizes that a number of sampling designs are acceptable, including simple random sampling, systematic sampling, stratified sampling, cluster sampling, or a combination of these. *Id.* § 3.10.4.

As stated above, the level of uncertainty that may be part of a sampling design can be addressed when the results of the sample are used to estimate the total overpayment. Section 3.10.5.1 of the Manual addresses this as follows:

> In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe. The method is equivalent to dividing the total sample overpayment by the selection rate. The resulting estimated total is called the point estimate of the overpayment, i.e., the difference between what was paid and what should have been paid. In stratified sampling, an estimate is found for each stratum separately, and the weighted stratum estimates are added together to produce an overall point estimate.
>
> In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. *This*

> *procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate.* However, the PSC or Medicare contractor [Benefit Integrity] unit is not precluded from demanding the point estimate where high precision has been achieved.

MPIM Ch. 3, § 3.10.5.1 (emphasis supplied).

The MPIM further discusses stratified sampling. MPIM Ch.3, §§ 3.10.4.1.3, 3.10.11.1. Notably, the MPIM states that "there is a method of 'optimal allocation,' i.e., one designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata." *Id.* § 3.10.11.1. However, the MPIM also states that "even if the allocation [of sample claims among strata] is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample." *Id.*

In discussing sample size, CMS explains that contractors must consider multiple factors in designing a statistical sample, including resource availability:

> [R]eal-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or Medicare contractor [Benefit Integrity] unit shall also consider their available resources. *That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit* as it fails to take into

> account all of the other factors that are involved in the sample design.

MPIM Ch. 3, § 3.10.4.3 (emphasis supplied). The MPIM further provides that if a decision on appeal upholds the sampling methodology, but reverses one or more claims determinations, the contractor recalculates the overpayment "and a revised projection of overpayment issued." *Id.* § 3.10.9.2.

A contractor must keep sufficient documentation of the statistical sampling methodology "so that the sampling frame can be re-created, should the methodology be challenged." MPIM Ch. 3, § 3.10.4.4.1. The "total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame." *Id.* § 3.10.5.1. "In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe." *Id.* (CMS explains that the term "bias" in statistical sampling is used in a technical sense and does not reflect unfair treatment of a provider or supplier. MPIM Ch. 3, § 3.10.5.1. "A biased estimator is often used rather than an unbiased estimate because the advantage of its greater precision outweighs the tendency of the point estimate to be a bit high or low." *Id.*) This process results in the "point estimate of the overpayment," which is "the difference between what was paid and what should have been paid." *Id.* In stratified sampling, estimates are obtained for each stratum and "the weighted stratum estimates are added together to produce an overall point estimate." *Id.*

CMS guidance provides that, "[i]n most situations, the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery . . . ." MPIM Ch. 3, § 3.10.5.1.[1] The lower limit calculation involves subtracting a multiple of the estimated standard error from the point estimate, thereby "yielding a lower figure." *Id.* "This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier." *Id.* This procedure results in an amount "that is very likely less than the true amount of overpayment"

[1] This is equivalent to a two-sided 80 percent confidence interval as used in RAT-STATS.

and "allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate." *Id.*

Homebound Status

To qualify for Medicare coverage of home health services, a beneficiary must be confined to the home, under the care of a physician, in need of skilled services, under a plan of care, and the services must be provided by a participating home health agency. 42 C.F.R. § 409.42. To be considered "confined to the home" or homebound, a beneficiary should either, due to illness or injury, require the aid of supportive devices or the assistance of another person to leave home or have a condition such that leaving home is medically contraindicated. Section 1814(a) of the Act; Medicare Benefit Policy Manual (MBPM)(Pub. 100-02) Ch. 7, § 30.1.1. In addition, the beneficiary must have a normal inability to leave home and leaving home requires a considerable and taxing effort. *Id.*

A beneficiary who leaves the home may still be considered homebound if the absences are infrequent or for periods of relatively short duration, including attendance at a religious service. Section 1814(a) of the Act; MBPM Ch. 7, § 30.1.1. In addition, a beneficiary may still be considered homebound if absent from the home to receive health care treatment, including to participate in therapeutic, psychosocial, or medical treatment in an adult day care program. *Id.*

Skilled Nursing and Rehabilitation Services

If a beneficiary qualifies for home health services because they are homebound (and meet the other criteria in 42 C.F.R. § 409.42), it is then necessary to consider whether the beneficiary required and received skilled services. To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. 42 C.F.R. § 409.32(a). Services that could qualify as skilled nursing include observation and assessment of a patient's changing condition, overall management and evaluation of a care plan, and patient education services. 42 C.F.R. §§ 409.33(a)-(c).

Nursing observation and assessment are covered skilled services "when the likelihood of change in a patient's condition requires

skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized." 42 C.F.R. § 409.33(a)(2); *see also* MBPM Ch. 7 § 40.1.2.1.

Overall management and evaluation of care plan constitute skilled services when the development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. Those activities include the management of a plan involving a variety of personal care services only when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel. 42 C.F.R. § 409.33(a)(1).

Further, in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self-administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be

regarded as a skilled service even if a nurse actually provides the service. 42 C.F.R. § 409.42(c)(1)(i).

Medicare guidelines also state that patient education services may be considered skilled nursing services. MBPM Ch. 7 § 40.1.2.3. Skilled nursing services for teaching and training are "reasonable and necessary where the teaching or training is appropriate to the patient's functional loss, illness, or injury." *Id.* In addition, in the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury. 42 C.F.R. § 409.42(c)(1)(ii).

Skilled therapy services must also meet the requirements of 42 C.F.R. § 409.44(c).

Home Health Prospective Payment System

Home health services are paid under a prospective payment system (PPS) which uses a case-mix index that measures the relative difference in resource intensity among different groups in the clinical model. 42 C.F.R. Part 484, Subpart E. A standard 60 day episode is the unit of payment, specific to one individual homebound beneficiary. Medicare Claims Processing Manual (MCPM) (Pub. 100-04) Ch. 10, §§ 10.1.4-10.1.5. Each home health claim must report all services provided to the beneficiary within the episode. Each service must be reported in line item detail, and each service visit per revenue code type of service must be reported as a single line. *Id.* § 40.2. A single home health claim may include multiple line items for each date of service and type of service. The PPS flat-rate payment encompasses payment for all line item services within an episode of care.

DISCUSSION

I. The Appellant's Arguments Concerning "Substantial Evidence" Review Provide No Basis for Reversing or Remanding the ALJ's Decision.

The appellant begins by arguing that the Council is "charged with determining whether the ALJ's decision is supported by substantial evidence in the record." Exh. MAC-1, at 2-3. This is an incorrect statement of the standard of review. As noted, the Council conducts a de novo review of the administrative record, limited to the exceptions presented in the request for review. 42 C.F.R. § 405.1100(c), 405.1112(c). The appellant is required to identify with specificity those portions of the ALJ's decision with which it disagrees and to provide, also with specificity, the evidentiary and legal bases for its disagreement. 42 C.F.R. § 405.1112(b).

The Council has reviewed the ALJ's comprehensive and well-reasoned 171 page decision, involving the statistical sample and overpayment extrapolation for sampled claims for the 27 beneficiaries listed in the request for review, and examined the administrative record contained in ten boxes of case files. The Council's review indicates that the ALJ considered the entire administrative record in reaching her decision and addressed all material evidence and the appellant's contentions. The ALJ's decision contains multiple references to, among other things, hearing testimony by expert witnesses and applicable Medicare standards for coverage, reimbursement, and statistical sampling. The ALJ explained her reasons for rejecting certain arguments and evidence proffered by the appellant. An ALJ who identifies the key legal issues, most important legal and policy authority, and relevant facts (as the ALJ did in this case) is not required to cite, reference, or consider every possible legal or policy source, or piece of evidence. *See* 42 C.F.R. § 405.1046(b)(ALJ decision must be written in a manner calculated to be understood by a beneficiary and include the specific reasons for the determination).

Despite the appellant's vigorous efforts to dissect the evidence in a manner most favorable to it throughout its 55 page request for review, on *de novo* review the Council concludes that the weight of the evidence of record is consistent with the ALJ's conclusions concerning coverage and the validity of the statistical sample and extrapolated overpayment. The Council agrees that the statistical sample and extrapolation methodologies are valid and examines claims for services listed in the attachment in response to the appellant's contentions, below. The Council finds no basis for overturning the ALJ's decision, however, based on the appellant's multiple arguments

throughout its filings that the ALJ failed to consider the entire administrative record.

II. The Appellant's Arguments Concerning Legal Error Provide No Basis for Reversing or Remanding the ALJ's Decision.

The Council has considered the appellant's arguments concerning legal error and, as set forth below, finds no basis for reversing the ALJ's decision on these issues. *See* Exh. MAC-1, at 3-8.

First, the appellant argues that the ZPIC may not extrapolate the unfavorable coverage determinations in the sample to the universe because to do so would amount to denying claims based on a "rule of thumb," rather than on individualized review of each beneficiary's medical record. Exh. MAC-1, at 3-4, *citing* MBPM Ch. 7, § 20.3. Apparently, the appellant is referring to the prohibition on the use of "rules of thumb" in medical review, to the detriment of an assessment of each beneficiary's individual care needs. *See also* 42 C.F.R. § 409.44(a). Under these authorities, denial of services based on numerical utilization screen, diagnostic screens, diagnosis or specific treatment norms is not appropriate.

However, these authorities were never intended to preclude extrapolation of the results of a sample, provided that the review of each individual beneficiary's needs was based on the unique medical condition that beneficiary and their individual need for care. As the ALJ recognized during the hearing, the application of such a rule, as argued by the appellant, would preclude the use of statistical sampling and extrapolation for overpayment estimation in any case involving home health services. CD at 10:28. The appellant points to no authority for such a sweeping proposition, and the Council is aware of none. *See generally* CMS Ruling 86-1 (statistical sampling in Medicare overpayment cases). As Congress has repeatedly recognized, the overarching need to protect the integrity of the Medicare trust funds requires administratively feasible claims review. The Council concludes that the asserted "rule of thumb" prohibition is not a bar to the extrapolation of the overpayment in this case.

Next, the appellant argues that the record does not support that the contractor identified a reason for statistical sampling and extrapolation and that the contractor failed to provide any

educational efforts in response to a purported high payment error rate. Exh. MAC-1, at 4-5. During the hearing, the ZPIC's statistician testified that the appellant was selected for claim review because data review indicated that the appellant was the "highest in the state of Texas for having a pattern of continuous episodes" of home health services for home health beneficiaries. Dec. at 5-6; CD at 11:28. It was reasonable for the contractor to apply its expertise to the data regarding the appellant's high billing rates and make reasonable inferences that billing of this magnitude was indicative of a sustained or high level of payment error, in order to perform post-payment review. Such claim review by the ZPIC is expressly contemplated and authorized by statutes governing the Medicare Integrity Program. *See, e.g.*, Sections 1893(a),(b) of the Act. Statistical sampling of large volumes of claims is also clearly authorized by CMS in Ruling 86-1, and CMS rulings are binding on ALJs and the Council. 42 C.F.R. § 405.1063(b). Moreover, the relevant statute specifically provides that a contractor's determination of a high payment error rate as a basis for extrapolation, based on its expertise, is not subject to either judicial or administrative review. Section 1893(f)(3) of the Act. Medicare regulations also provide that "[d]eterminations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act" are not initial determinations and have no appeal rights. 42 C.F.R. § 405.926(p). Moreover, the contractor's determination to reopen (which would include the reasons for reopening) are binding and not subject to appeal or review by the Council. 42 C.F.R. §§ 405.926(1) and 405.980(a)(5). The Council finds no basis in this argument for changing the ALJ's decision.

The appellant also argues that the ALJ erred in applying 42 C.F.R. § 405.1064, which provides that, in a case involving an overpayment derived by statistical sampling, "an ALJ must base his or her decision on a review of the entire statistical sample used by the QIC." Exh. MAC-1, at 6-7. The appellant's argument, in essence, is that the ALJ erred in reviewing claims decided favorably to the appellant at lower levels of appeal. *Id.* at 6-7. Medicare regulations generally provide that the issues before an ALJ include "all the issues" brought out in the initial determination, redetermination, and reconsideration "not decided entirely in a party's favor." 42 C.F.R. § 405.1032(a). However, the regulations also provide that "if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the

hearing." *Id.* The notices of hearing and the pre-hearing conference order issued by the ALJ in this case clearly state that the ALJ would review all claims in the statistical sample, which would include claims previously decided favorably to the appellant. Exhs. 9, at 2; 18, at 2; 21, at 2. The scope of this review was within the ALJ's discretion. Given this pre-hearing notice, the Council finds that the ALJ did not err in reviewing all claims in the statistical sample at the hearing or in her decision. As the ALJ provided notice of this issue before the hearing, the Council need not and does not further analyze 42 C.F.R. § 405.1064 for this case.

Lastly, the appellant argues that both CMS and the contractor erred in *proposing* to recoup the purported overpayment before timelines set forth in section 1893(f) of the Act. Exh. MAC-1, at 7, *citing* 42 U.S.C. § 1395ddd(f). (In any event, the appellant has not cited to any evidence of actual recoupment.) Regulations governing Medicare appeals confine the Council's review to coverage of the home health services in the statistical sample and liability for non-covered charges and any resulting overpayment, if any. *See, generally,* 42 C.F.R. § 405.924(b) (initial determinations). Any determination regarding suspension of payment, offset, or recoupment under 42 C.F.R. § 405.372 is not an initial determination and is not appealable. 42 C.F.R. § 405.375(c). Thus, any contractor action with respect to the timing of recoupment does not affect the validity of the overpayment. The appellant also asserts that the regulations violate the statute, but the Council is without authority to pass on the validity of a regulation. 42 C.F.R. § 405.1063. The Council therefore finds no basis in this argument for changing the ALJ's decision.

III. The Appellant's Arguments Concerning Statistical Sample and Extrapolation Invalidity Are Insufficient To Reverse or Remand the ALJ's Decision.

As noted above, CMS Ruling 86-1 establishes a presumption of validity that attaches to the statistical sampling and extrapolation undertaken by a Medicare contractor. CMS Ruling 86-1-9, 86-1-10. The burden of proof is on the appellant to demonstrate that the methodology used by the contractor is invalid. *Id.* The Council concludes that the appellant has failed to meet this burden.

ALJ Decision

The ALJ recounted in significant detail the testimony of the appellant's statistical experts (Dr. C. and Dr. W.) concerning issues raised again in the request for review. Dec. at 4-5. The ALJ also recounted testimony from the ZPIC's statistician, H.P., concerning how the appellant was selected for review and the design and execution of the statistical sample. *Id.* at 5-7, *citing* MPIM Ch. 8, *passim*. In relevant part, the ALJ recounted H.P.'s testimony regarding sample design as follows:

> Ms. [P.] testified that the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, § 8.4.1.3 [Ch. 3, § 10.1.3] describes the steps for conducting a statistical sample. It states:
>
> The major steps in conducting statistical sampling are: (1) Selecting the provider or supplier; (2) Selecting the period to be reviewed; (3) Defining the universe, the sampling unit, and the sampling frame; (4) Designing the sampling plan and selecting the sample; (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) Estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collections of the overpayment.
>
> Ms. [P.] argued that Health Integrity complied with these steps.
>
> Ms. [P.] testified that the universe was defined as all claims from beneficiaries with five plus (5+) home health care episodes with payments between $1,000 and $6,000 billed for services rendered between July 1, 2006 and July 31, 2009. There were 10,699 claims for which the Appellant was paid a total of $26,522,686.00.
>
> Ms. [P.] testified that the sample [unit] was each claim. A two (2) strata sample was used with 27 claims in each stratum for a total of 54 claims in the sample. Stratum one (1) was for claims with payments between $1,000 and $3,000. Stratum two (2) was for claims with payments between $3,000 and $6,000. The 54 claims were randomly selected in such a manner that

> each and every claim in the universe had an equal probability of being selected. Ms. [P.] testified that the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, § 8.4.11.1 [MPIM Ch. 3, § 3.10.11.1] states that generally 'a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying.' Ms. [P.] pointed out that this section also states 'that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.'
>
> Ms. [P.] further testified that in accordance with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, § 8.4.4.2 [MPIM Ch. 3, § 3.10.4.2] Health Integrity used the software statistical package RAT-STATS. Pursuant to the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, § 8.4.5.1 [MPIM Ch. 3, § 3.10.5.1], Health Integrity used the lower limit of the one-sided 90 percent confidence interval. Ms. [P.] explained that this is a conservative method and works to the financial advantage of the provider.

Dec. at 6; *see also id.* at 52-53.

In response to testimony by the appellant's statistical experts, the ZPIC's statistician, H.P., testified that "using a data analysis instead of a probe sample complies with Medicare guidelines." Dec. at 7, *citing* MPIM Ch. 8, § 8.4.1.4 (MPIM Ch. 3, § 3.10.1.4). H.P. also testified that "pursuant to both the visual check of distribution and the statistical hypothesis testing for differences, the results both demonstrated that the sample is representative of the universe." *Id.* H.P. then testified that "the precision in this case is not unusual," "there is always uncertainty in sample design," and using "the lower bound of a 90% confidence interval accounts for lack of precision to Appellant's advantage." *Id.* H.P. stated that underpayments found on medical review are factored into the extrapolation and the 75% error rate used in sample design was based on proactive data analysis that identified the appellant as the "number one (1) facility for continuous episodes of home health services," with an actual error rate of 54%. *Id.*

In response to H.P.'s testimony, appellant's statistical expert Dr. C. "testified that he agreed with many of Ms. [P.'s] points." Dec. at 7. With respect to whether the sample was sufficiently representative, Dr. C. testified that "a larger sample would have worked better" and would have prevented problems with "clustering." *Id.* Dr. C. also testified that excluding underpayments as zero paid claims, and not sampling claims under $1,000.00, was prejudicial to the appellant. *Id.* Appellant's second statistical expert, Dr. W., testified that, given the definition of the universe of sampled claims, "it was impossible for underpaid claims to be a part of the universe." *Id.* Dr. W. also testified that the 75% assumed error rate, when compared to the actual 54% error rate, "demonstrates that the proactive analysis was wrong." *Id.* Dr. W. then testified that "clustering is a big issue." *Id.*

After considering this testimony and the record, the ALJ stated that Medicare policy provided that "[s]o long as proper procedures for the execution of probability sampling have been followed . . . [a] challenge to the validity of the sample . . . is without merit as it failed to take into account all of the other factors that are involved in the sample design." Dec. at 52, *citing* MPIM Ch. 3, § 3.10.4.3. The ALJ determined that the ZPIC demonstrated that "'proper procedures' were followed." *Id.* The ALJ reviewed the testimony of the ZPIC's statistician, H.P., regarding sample design and execution under MPIM guidelines. *Id.* at 52-53. The ALJ noted that the appellant's statistical experts, Dr. C. and Dr. W., "agreed with many of Ms. [P.'s] points." *Id.* at 53. While also noting testimony of appellant's experts that "a larger sample size would have been better," the ALJ concluded that the appellant had not met its burden of proving that the contractor had not complied with Medicare requirements for statistical sampling. *Id.* The ALJ affirmed the validity of the statistical sample. *Id.* at 53-54.

Appellant's Request for Review

The appellant presents multiple arguments that the statistical sample and extrapolation are invalid. First, the appellant argues that the ALJ erred in evaluating manual provisions which require that elements of a probability sample must be "properly executed." Exh. MAC-1, at 44-46, *citing* MPIM Ch. 3, § 3.10.2. As examples, the appellant states that the contractor erred in extrapolation because the formulas assumed variable value in claims (continuous data), while its expert had opined that the claims were "not continuous." *Id.* at 45. The appellant also

states that the contractor calculated confidence intervals using RAT-STATS software formulas that assumed application of the Central Limit Theorem, while claim distribution "does not fit the CLT" due to data clustering. *Id.* The appellant also asserts that the contractor erred by "us[ing] the wrong formulas . . . when as a part of its extrapolation it applied the 50% error rate uniformly across the sample." *Id.* at 45-46. The appellant states that "larger claims . . . were less likely to have errors" than smaller claims. *Id.* at 46.

The appellant next argues that the ZPIC's statistical sample and extrapolation must meet the test for scientific evidence established by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579 (1993). Exh. MAC-1, at 46-48. Generally, the appellant argues that the ALJ erred in upholding the statistical sample and extrapolation after the appellant had "presented . . . results of scientific tests [performed by its statistical experts] showing the errors in the contractor's work" and demonstrated that the contractor used incorrect formulas in at least three instances. *Id.* at 48.

The appellant then argues that the ALJ erred in ignoring "tests" by its experts purporting to demonstrate that the sample was not representative of the universe. Exh. MAC-1, at 48-51. The appellant argues that its experts demonstrated "inconsistencies in the mean number of claims per beneficiary and standard deviation [sic] number of claims per beneficiary." *Id.* at 49 ("clustering test"). The appellant also argues that its experts demonstrated that the sample did not meet "billing code," "denial code," and "diagnostic code" tests. *Id.* The appellant maintains that the contractor "has presented no credible evidence that the sample was representative" to counter these results. *Id.* at 49-50.

Finally, the appellant argues that the ALJ applied incorrect standards in evaluating the "accuracy and procedural correctness" of the statistical sample and extrapolation. Exh. MAC-1, at 51-54. The appellant states that its experts opined that the sample size was "too small by a factor of almost three times," based on incorrect data entered into the RAT-STATS program. *Id.* at 51. The appellant also states that the ZPIC's review should have been based "on the accuracy of a probe sample or something equivalent." *Id.* at 52. The appellant then states that the precision rate in the strata did not meet standards set forth in OMB Circular A-123 Appendix C. *Id.* at 52-53. The appellant concludes that the application of the lower bound of

the confidence level does not correct the sample flaws based on "sloppy precision." *Id.* at 53.

A. The record supports the presumption that the sampling and extrapolation were valid.

The MPIM requires that a Medicare contractor follow six steps in conducting a statistical sample for overpayment estimation:

1. Select the provider or supplier.
2. Select the period to be reviewed.
3. Define the universe, sampling unit, and sampling frame.
4. Design the sampling plan and select the sample.
5. Review each of the claims or line(s) on the claim and determining if there was an overpayment, or, for administrative reviews, an underpayment; and, as applicable,
6. Estimate the overpayment.

MPIM Ch. 3, § 3.10.1.3.

As noted above, the ZPIC's statistician, H.P., opined in writing and in testimony that the sampling and extrapolation in the present case satisfied all MPIM requirements. The Council's review supports this conclusion.

The contractor selected the appellant for post payment review based on data analysis showing an unusually high number of claims involving five plus consecutive home health episodes during the specified period. Dec. at 6; *see also* Exh. 6, at 4-5 (ZPIC Sampling Methodology Memorandum). The ZPIC's sampling documentation provides that the universe of claims consisted of "all claims from beneficiaries with 5 or more full home care episodes and claims with payments between $1000 and $6000 for which Palm Valley Healthcare billed for services rendered between the period of July 1, 2006 and January 31, 2009. There were 10,699 claims for which Palm Valley Healthcare was paid a total of $26,522,686.00." Exh. 6, at 4. The sampling unit was "each claim," and "a 2 strata sample was used, with 27 claims in each stratum for a total of 54 claims in the sample." *Id.* "The 54 claims were randomly selected from the 10,699 claims in the universe." *Id.* The selection of the claims for the strata was made using the SAS program, such that each claim had an equal chance of being selected. *Id.* The sampled claims included 7 revenue codes and a total of 1,466 claim lines. *Id.* at 9.

The ZPIC reviewed the sample claims and determined that the appellant had been overpaid as to 29 of the 54 claims in the two strata, for a service error rate of 54%. Exh. 6, at 13. The total overpayment calculated for the sampled claims was $81,681.03. *Id.* at 7. The ZPIC extrapolated the results of the sample to the universe and calculated that an extrapolated overpayment amount of $12,589,185 would be recouped, which represented the lower limit of a one-sided 90 percent confidence interval. *Id.* The sample precision was 16%. *Id.*

The appellant does not challenge the randomness of the sample or argue that it was not a probability sample. Based on the sampling documentation and testimony of the statistical experts, the Council concludes that the sampling at issue resulted in a probability sample, giving rise to the presumption that the projected overpayment amount is valid, as set forth in CMS Ruling 86-1. The Council next considers whether the appellant's objections to the sampling and extrapolation are sufficient to overcome this presumption.

B. Alleged failures of the contractor to follow MPIM guidance do not render the statistical sampling invalid.

CMS guidance provides that a contractor's failure to adhere to one or more elements described in the MPIM "may result in review by CMS of [the contractor's] performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment." MPIM Ch. 3, § 3.10.1.1. In the present case, the perceived shortcomings in the ZPIC's methodology, as identified by the appellant's statistical experts, do not demonstrate that the sampling and extrapolation were invalid. In reaching this conclusion, the Council notes the testimony of the appellant's statistical expert, Dr. C., that he had no argument with the ZPIC's selection of the appellant for claim review. CD at 12:00-12:05. Dr. C. also testified that he agreed with the ZPIC's statistician that the formulas used were found in standard textbooks on statistical sampling, were implemented with the RAT-STATS software program, and were "statistically valid." *Id.* Dr. C. further testified that he found no problem with the sample itself, which he testified was a probability sample. *Id.* Dr. C. then stated that the primary problem in this case was the "tiny sample" and that the contractor "could have" chosen a different sampling unit, although it was not

required. *Id.* These points, as well as the appellant's contentions, are addressed below.

1. Statistician Qualifications

In its final argument, the appellant asks that the Council consider the credentials of the respective statistical experts in assessing sample validity. Exh. MAC-1, at 53-54. The appellant argues that both of its statistical experts have Ph.D. degrees, are fellows of the American Statistical Association, and one "studied at Harvard under W. Cochran," a respected authority in statistical sampling. *Id.* The record demonstrates that ZPIC statistician H.P. reviewed the sampling methodology. *See, e.g.*, Exh. 6, at 7-9. Her curriculum vitae is in the record and indicates that she is the Chief Statistician for the Zone 4 ZPIC, has a master's degree in Applied Statistics, and is currently a candidate for a Ph.D. degree in Computational Statistics. Exh. 27, at 6. CMS requires that a contractor's sampling methodology, used to project an overpayment, be reviewed by "a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. . . . At a minimum, the statistical expert (either on-staff or consultant) shall possess a master's degree in statistics *or have equivalent experience.*" MPIM Ch. 3, § 3.10.1.5 (emphasis supplied). The ZPIC's statistician in this case, H.P., meets these requirements.

In any event, even if the record did not demonstrate that the sampling methodology was reviewed by a statistician with the requisite qualifications, this factor, without more, would not demonstrate that the sampling method is invalid. The Council rejects the appellant's argument that the standard for "scientific knowledge," as established by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), is sufficient to invalidate the statistical sample as drawn in the case. *See* Exh. MAC-1, at 46-48. This argument largely bootstraps the arguments that the sample was not representative, and thus invalid, because it did not precisely mirror the universe in several ways, according to appellant's witnesses. The ZPIC's statistician, as well as the appellant's witnesses, have all cited generally accepted statistical principles, even if there may be differences of opinion as to which principles should control. We explain below why the merits of appellant's arguments are not persuasive. The sample in this case comports with MPIM criteria for a valid sample.

2. Probe Sample

During hearing testimony, appellant's statistical expert Dr. W. faulted the statistical sample on grounds that the contractor did not conduct a probe sample. CD at 10:49-10:54; *see also* Dec. at 4 (Dr. C. testimony on probe sample). The ZPIC's statistician testified that using data review in lieu of a probe sample to determine a payment error rate was allowed under CMS authority. Dec. at 53, *citing* MPIM Ch. 8, § 8.4.1.4 (MPIM Ch. 3, § 3.10.1.4). The ALJ determined that the contractor had fulfilled its obligations, under manual authority for statistical sampling and methodology. *Id.* The Council agrees.

Nothing in CMS Ruling 86-1 or the MPIM suggests that a probe sample is required before a statistical sample for overpayment estimation may be drawn. Instead, MPIM guidance governing probe samples is directed to Medicare Administrative Contractors conducting post-payment medical review, rather than to ZPICs conducting program integrity activities. The MPIM provides:

> Before deploying significant medical review resources to examine claims identified as potential problems through data analysis, [Medicare Administrative Contractors shall] take the interim step of selecting a small "probe" sample of potential problem claims (prepayment or postpayment) to validate the hypothesis that such claims are being billed in error. This ensures that medical review activities are targeted at identified problem areas. Such a sample should be large enough to provide confidence in the result, but small enough to limit administrative burden.
>
> For post-pay review of an individual provider in the case of a possible provider specific problem, contractors should include in the probe sample a random or stratified sample of generally 20-40 claims from that provider with dates of services from the period under review. . . . .

MPIM Ch. 3, § 3.11.1.2. The point to be made here is not that a ZPIC may not conduct a probe sample in an appropriate case, only that it is not *required* to do so before proceeding with drawing a statistical sample for overpayment determination and extrapolation. Thus, the absence of a probe sample does not invalidate the sampling and extrapolation in the present case.

Moreover, this argument actually appears to challenge the ZPIC's reasons for selecting the appellant for post-payment review. As previously stated, the record supports that the ZPIC selected the appellant based on data analysis, as contemplated under the Medicare Integrity Program, which indicated that the appellant was the highest biller for a pattern of continuous episodes of home health services in the State of Texas. Dec. at 6. As explained previously, the contractor's determination to reopen based on this data analysis is not subject to review by the Council. The ZPIC's decision to extrapolate the overpayment to the universe of claims, based on a high payment error (in this case, 50%) is also not subject to review by the Council in this appeal. Section 1893(f)(3) of the Act; 42 C.F.R. § 405.926(p); *see* Exh. 6, at 7. The failure of the ZPIC to conduct a probe sample as a basis for determining payment error rate is not a basis for invalidating the statistical sample and extrapolation.

3. Representative Sample/Normal Distribution (Central Limit Theorem)

The appellant argues at various places that the ALJ erred in failing to consider the numerous "tests" conducted by its experts which purport to demonstrate that the statistical sample was not representative of the universe of claims from which it was drawn. Exh. MAC-1, at 48-51. In support, the appellant points to a test conducted on "claims per beneficiary," which it also refers to as the "clustering test," demonstrating that the "mean number of claims per beneficiary" and "standard deviation number of claims per beneficiary" show that the sample was not representative of the universe. *Id.* at 49. (The appellant also refers to "billing-code," "denial code," and "diagnostic code" tests, set forth in the written reports of its statistical experts, as supporting the non-representative nature of the sample. *Id.*; *see* Exhs. 24, at 1-13; 30, at 48-55.)

The ALJ's decision discusses these arguments, as set forth in appellant expert testimony. Dec. at 6-7. The ALJ recounted the ZPIC statistician's response that, based on "both the visual check of distribution and the statistical hypothesis testing for differences, the results both demonstrated that the sample is representative of the universe." *Id.* at 7. The ALJ then reviewed the response of the appellant's expert, Dr. C., that he agreed with the ZPIC's statistician on many points, including the following: "Regarding representation, [Dr. C.] testified

that a larger sample would have worked better. By using a small sample, there were issues with clustering, etc." *Id.*

There is no support in CMS Ruling 86-1 or the MPIM for the proposition that non-normality of the average of sampling units within a single sample demonstrates that the sample is statistically invalid. The relevance of the Central Limit Theorem in this case, as in many of the overpayment cases involving statistical sampling, is that it demonstrates that a single sample of limited size is sufficient to obtain a representative sample *even if* overpayments or other sample factors are not normally distributed. This is because the mean of a large number of repeated samples will tend to follow a normal distribution, under these circumstances. As indicated, the ZPIC's statistician opined that the statistical sample as drawn reflected normal distribution. The appellant's expert testified that the sample in this case was a probability sample and that the formulas used in calculating the overpayment and extrapolation were taken from standard texts on statistical sampling and were statistically valid. CD at 12:00-12:03. The appellant's argument that the ZPIC erroneously applied a 50% payment error rate uniformly "across the sample" when extrapolating the overpayment (id.) also ignores the record evidence which indicates that the statistical sample was a probability sample that used valid sampling formulas for claim selection and overpayment extrapolation. The Council finds no basis in these contentions for changing the ALJ's decision.

Moreover, the sampling unit employed was the claim, not the beneficiary, billing code, denial code, or diagnostic code (tests referenced by the appellant's experts). While the appellant argues that "larger claims were less likely to have errors" than smaller claims, the appellant has not shown that the 54 claims allocated between the two strata, based on payment amount, were not representative of the universe from which they were selected. *See, e.g.*, Exh. MAC-1, at 45-46. In particular, we note that the appellant's assumptions and calculations underlying the points presented in Exhibits 24 and 30 are largely unexplained or do not withstand critical analysis. For example, the appellant vigorously asserts that the representativeness of the sample is "so far off the usual scale that it corresponds to the proverbial monkey typing Shakespeare's complete works word for word," because the universe had a mean of 8.42 claims per beneficiary, while the sample had only 1.02 claims per beneficiary. This might be a meaningful difference if the beneficiary was the sampled

variable, rather than the claim. However, it is obvious from a cursory review of the definition of the universe (and the actual start of care dates for the sample beneficiaries) that all beneficiaries in the sample had at least five episodes of care. It is not surprising though, that the number of claims actually reviewed *for each beneficiary* in the sample was not the same as the total number of claims filed for each beneficiary, because each claim was the independent sampling variable.

Dr. C. did testify that the contractor "could have chosen" different sampling units. CD at 12:03-12:05. Dr. C. also testified that standards for "yes/no" and continuous sampling methodologies, as set forth in the statistical sampling treatise authored by W. Cochran and in the "body of statistical literature," demonstrates flaws in the ZPIC's methodology. *Id.* at 11:04-11:09; *see also* Exh. MAC-1, at 45. Dr. W. also testified that diagnostic and denial codes were "reasonable" variables to look at in relation to whether the sample is representative of the universe. *Id.* at 12:05-12:06. However, the appellant appears to have selectively chosen isolated denial codes or diagnostic codes without meaningfully explaining the significance of these codes.

The thrust of these arguments, then, is that the appellant's experts may have designed the statistical sample in this case differently than the ZPIC, possibly with standards incorporated from academic treatises which seek greater precision in sampling. Suffice it to say, however, that given provisions in the MPIM and CMS Ruling 86-1, the fact that the ZPIC selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, provides no basis for invalidating the sampling or the extrapolation as drawn and conducted *in this case*. (We note that the appellant has not preserved for review the argument of its statisticians that the universe was invalid because it did not include all zero paid claims. The MPIM does not require the ZPIC to expend limited resources to review claims denied and unpaid.) These are simply not "flaws" in the sampling recognized by the administrative guidelines as bases for rendering the actual sample drawn invalid. To hold otherwise would ignore real world constraints imposed by conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines. The Council must give substantial deference to CMS guidelines, including where, as here, CMS chose a reasonable, feasible, and well-articulated approach for collecting

overpayments which, by design, offsets precision in favor of lower recovery amounts. To the extent that Dr. C., Dr. W., or another statistician have significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised with CMS, as the Council has no authority to invalidate CMS guidelines.

4. Precision

The appellant argues that the ALJ erred in upholding the statistical sample despite differences in precision rates between the sample design and the results achieved. Exh. MAC-1, at 52. In support, the appellant points out that OMB Circular A-123, Appendix C requires federal agencies conducting statistical sampling and extrapolation to attain a precision of plus or minus 2.5 percentage points with a 90 per cent confidence level. *Id.* at 52-53. The appellant therefore contends that the sampling and extrapolation in the present case are invalid based on lack of precision. *Id.*

The ALJ stated that the ZPIC's statistician testified that the "precision in this case is not unusual." Dec. at 53. The ZPIC's statistician also testified "that there is always uncertainty in sample design," but that "the lower bound of a 90% confidence interval incorporates the precision. It accounts for lack of precision to the Appellant's advantage." *Id.* The ALJ also stated during the hearing that her review indicated that the OMB Circular applies to Medicaid cases. CD at 10:31-10:34.

The MPIM repeatedly addresses precision in a statistical sample and makes clear that a provider whose claims are being audited is protected from a degree of imprecision or uncertainty by limiting overpayments to the lower level of a ninety percent one-sided confidence interval. MPIM Ch. 3, § 3.10.5.1. The appellant's assertion that the precision is not 16%, but 23% overall is largely unexplained. Exh. 24. The appellant points to no evidence or authority which indicates that the 16% (or 23%) precision actually obtained in this case is beyond the range of acceptable results contemplated by the MPIM. *See* Exh. 6, at 7.

The Council has also reviewed OMB Circular A-123, Appendix C. *See* http://www.whitehouse.gov/sites/default/files/omb/assets/a123/a123_appx-c.pdf The purpose of Appendix C is to implement the requirements of the Improper Payments Information Act of 2002

(IPIA)(Pub. L. 107-300). The IPIA requires federal agencies to report to Congress annually the agencies' estimates of the amounts of improper payments made in programs that are susceptible to "significant erroneous payments." Appendix C defines "significant erroneous payments" as "those exceeding both 2.5 percent of program payments and $10 million." Thus, in the case of programs administered by the U.S. Department of Health and Human Services, the precision standard specified in Appendix C may apply to the Department's reporting of certain erroneous payments in the Medicare program *as a whole*, but does not apply to the calculation of an overpayment to an individual provider.

Similarly, the appellant cites to CMS rulemaking implementing its reporting requirements under the IPIA. Exh. MAC-1, at 53, *citing* 72 Fed. Reg. 50495 (August 31, 2007). The CMS rule, titled, "Medicaid Program and State Children's Health Insurance Program (SCHIP) Payment Error Rate Measurement," explains the sampling and extrapolation methodology CMS and states will use to estimate global improper payments in Medicaid and SCHIP, pursuant to the IPIA. *See* 72 Fed. Reg. 50490 (August 31, 2007). The rule does not by its terms apply to Medicare, or even to individual overpayment amounts in Medicaid or SCHIP.

The appellant's citations to Appendix C and to the Medicaid and SCHIP rule represent an attempt to incorporate by reference standards requiring greater precision than CMS has adopted for the estimation of Medicare overpayments to individual providers. Moreover, the appellant's arguments that the ALJ was "too liberal" and provided "undue leeway" in applying the MPIM guidelines are unavailing. *See* Exh. MAC-1, at 51-54. As we have pointed out above, CMS Ruling 86-1 and the MPIM provide the standards that CMS has adopted for this purpose. These authorities do not specify a required level of precision and account for any lack of precision by the use of confidence interval assessments. The Council finds no basis in this argument for changing the ALJ's decision.

5. Sample Size

The appellant's statistical experts opined at various points that the statistical sample in this case was flawed, in part, because the sample was not large enough. CD at 12:03-12:05 (Dr. C. refers to "tiny sample"); *Id.* at 11:25 (Dr. W. states ZPIC did not choose correct sample size). This theory appears to be based on the fact the 50% error rate in the sample found after review was less than the 75% estimated error rate used to draw

the sample. However, we are without the benefit of a full explanation in Exhibits 24 and 30 of how the appellant's expert witnesses arrived at this conclusion.

As noted, the contractor defined the sampling unit as "each claim" and explained the universe as "claims from beneficiaries with 5 or more full home care episodes and claims with payments between $1,000 and $6,000" with dates of service "July 1, 2006, and July 31, 2009." Exh. 6, at 4. The contractor selected a universe consisting of 10,699 claims. *Id.* From that universe, using the SAS program, the contractor selected 54 claims, which were allocated to two strata based on payment amount. *Id.* The contractor determined the average overpayment per claim, for each strata, then determined an extrapolated overpayment of $12,589,185, at the lower bound of the 90% confidence level. *Id.* at 5. The contractor calculated a 50% error rate, based on overpayment amount. *Id.* at 7.

The Council finds no basis for overturning the statistical sample, as conducted in this case, based on the appellant's contentions that the sample size was inadequate. In relevant part, CMS explains as follows:

> In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or Medicare contractor [Benefit Integrity] unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. *A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.*

MPIM Ch. 3, § 3.10.4.3 (emphasis supplied). It was reasonable for the contractor to apply its expertise to the data regarding the appellant's high billing rates and make reasonable inferences about what the likely error rate would be, when determining the sample size. The fact that the actual error

rate, after medical review, was 50% rather than 75% does not invalidate the sample. It is not necessary for the contractor, after expending considerable limited administrative resources for medical review of the sample, to then draw another sample because the error rate turned out to be *only* 50%. As noted, Dr. C. testified that the sample conducted was a random probability sample. CD at 12:00-12:03. The appellant's main argument is again grounded primarily in the premise that a different sample would have been more precise. The Council finds no basis for invalidating the sample and extrapolation in this argument.

In sum, the Council concludes that the ALJ did not err in affirming the validity of the statistical sample and extrapolation in this case. The Council next addresses contentions that the ALJ erred in unfavorable or partially favorable coverage findings. As explained below, although we find that two beneficiaries were homebound, we find no error in the ALJ's ultimate determinations of non-coverage.

IV. Coverage of Home Health Services

A. Background

In the Decision Addendum (116 pages), the ALJ made detailed and comprehensive findings of fact concerning coverage of 53 claims for home health services provided to the beneficiaries. Dec. at 55-171; *see also id.* at 172-76 (Decision Reference). The Council incorporates those findings and conclusions herein.

Generally, the ALJ made fully favorable determinations for 25 claims and partially favorable or unfavorable determinations for the remaining 28 claims. *Id.* (The ALJ's Decision Reference erroneously characterizes the determination for Beneficiary P.B. as unfavorable when the Decision Addendum reflects a fully favorable determination. *Compare* Dec. at 172 *and* 68-70. The Decision Reference also erroneously characterizes the determination for Beneficiary F.M.2 as fully favorable when the Decision Addendum reflects an unfavorable determination. *Compare id.* at 174 *and* 107-08.) The appellant presents individual contentions for each of the 28 partially favorable or unfavorable determinations, generally arguing that the ALJ erred in determining that the beneficiary did not meet homebound eligibility requirements or that services do not meet Medicare skilled care requirements.

In this case, as in all Medicare appeals, the appellant has the burden to establish that it is entitled to Medicare payment. The Medicare statute and regulations make clear that it is the responsibility of the provider or supplier to furnish sufficient information to determine whether payment is due and the amount of the payment. Section 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6). Medicare hearing regulations further provide that the Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

B. Individual Claims - Homebound Status

The administrative record for each beneficiary generally includes individual claim folders from the initial certification period (start of care), the certification period immediately before the home health episode at issue, the home health episode at issue (dates of service), as well as an additional unmarked folder which contains various procedural and clinical documentation, including the Beneficiary Interview (BI). For identification purposes, the Council has marked the folder with the BI with an exhibit number and "A."

The Council has reviewed the appellant's contentions and the record for each beneficiary. The ALJ determined that the record for 22 beneficiaries (with 23 dates of service) did not support that the beneficiary was homebound and also, in some cases, that the services did not constitute skilled care. *See* Beneficiaries M.A., M.B., J.B., M.C., F.D., T.F., R.L., F.M.1, F.M.2, P.M., R.M., E.P., M.P., J.R. (2 episodes of service), B.S., M.S.2, A.S., M.S.3, O.T., L.V., M.Y., C.Z. In light of the appellant's contentions, the Council addresses each of these beneficiaries below. For the beneficiaries whom the Council also determines were not homebound, and thus do not qualify for coverage of home health services under Medicare, the Council does not also address the appellant's irrelevant contentions concerning the medical necessity of skilled services for these beneficiaries.

1. Beneficiary M.A. (ALJ #2) (10/07/08-12/05/08): The ALJ issued an unfavorable decision for services billed under code G0154 (skilled nursing or SN). Dec. at 58-60. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound or that she required skilled services. *Id.* at 60. The ALJ examined the BI in determining that, during the dates of service, the beneficiary did not

experience pain interfering with activity, have skin lesions or open wounds, or require assistance with activities of daily living (ADLs) or ambulation. *Id.* at 60. The ALJ noted that the beneficiary left home without an assistive device to attend church. *Id.* at 60. The ALJ also determined that the record did not establish that the beneficiary was "physically or mentally unable" to self-inject insulin for diabetes or reflected attempts to teach the beneficiary to administer insulin, to check her own blood sugar, or to identify an alternative caregiver. *Id.*

The appellant argues that the ALJ erred in finding the beneficiary not homebound because the record supports that the beneficiary experienced pain. Exh. MAC-1, at 8-9. The appellant also argues that the beneficiary had "skin lesions or open wounds," reflected in the record as "age spots each visit." *Id.* at 9. The appellant further argues that the beneficiary needed assistance with ADLs and used assistive devices for ambulation. *Id.* The appellant then argues that the record supports that the beneficiary had abnormal blood sugar ranges and that the beneficiary was unable to self-administer insulin injections. *Id.* at 10-11, *citing* MBPM Ch. 7, § 40.1.2.4. The appellant cites to the BI as evidence that the beneficiary was unable to self-inject insulin. *Id.* at 11-12.

The appellant's contentions for this beneficiary are the most extensive in the request for review. The Council sets forth a more thorough analysis in this instance to reflect the framework of review conducted for each claim.

The case record for this beneficiary includes four sets of multiple claim folders, containing documents from three different periods of time. Exhibit 4 (3 folders) contains documents from the beneficiary's start of care (SOC) and initial certification period, from April 21, 2006, through June 19, 2006. Exhibit 5 (2 folders) contains documents from the home health episode prior to the dates of service, from August 8, 2008, through October 6, 2008. Exhibit 6 (2 folders) contains documents from the dates of service at issue, October 7, 2008, through December 5, 2008. An unmarked single file folder also contains procedural documents and clinical records including ten (10) daily SN visit note reports, each day from October 7, 2008 (visit 1) through October 16, 2008 (visit 10). The unmarked file folder also includes the home health plan of care (POC) for certification period October 7, 2008, through December 5, 2008, as well as the contractor BI, dated August 19, 2009. The

Council marks this file folder as Exhibit 6A for identification purposes. The Council notes the documents in *each* set of file folders contain numerical stamps from 00001 through 00452 (Exhibit 4), 00327 (Exhibit 5), and 00308 (Exhibit 6). The documents in the file folder now marked as Exhibit 6A contain the documents cited by the ALJ. The appellant's request for review cites to documents found in Exhibit 6.

April 21, 2006-June 19, 2006 (M.A. Exh. 4)

The beneficiary was admitted to home health care with SOC date April 21, 2006. M.A. Exh. 4, at 25-27. Principal diagnosis was "unspecified osteoporosis," with other pertinent diagnoses diabetes mellitus without mention of complications, Type II; general osteoarthrosis; and unspecified essential hypertension. *Id.* at 25. The physician ordered SN visits twice a week for one week, seven times a week for eight weeks, and twice a week for one week. *Id.* The nurse was to provide SN observation and assessment services of all body systems, including reactions to medications, and the cardiac system to monitor response to hypertension. The nurse was also to provide SN teaching services related to hypertension and observation and assessment of pain control. *Id.* While this set of records contains two home health POCs for certification period April 21, 2006, through June 19, 2006, neither document is both signed and dated by the attending physician. *Compare id.* at 25-27, 28-30.

Visit note reports in the three folders for this period are almost all computer generated, are substantially similar, and indicate that the appellant provided 120 visits during this certification period. *See* M.A. Exh. 4, at 383-87. While these clinical records state that the beneficiary is homebound and cannot leave home without considerable and taxing effort, an entry on a Client Information Report, dated April 20, 2006, states the physician requested daily SN visits to administer Forteo injections. *Id.* at 443. An entry on the same document, dated April 27, 2006, indicates that the "PT WANTS TO BE SEEN BEFORE 10:00AM D/T PT LEAVING HOUSE @10:30AM TO CARE FOR HER ELDER FATHER." *Id.*

August 6, 2008-October 6, 2008 (M.A. Exh. 5)

The home health POC for certification period August 8, 2008, through October 6, 2008, indicates a change in principal diagnosis to diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled (ICD-9-CM code 250.52), with

other pertinent diagnoses vision impairment both eyes, obstructive chronic bronchitis without exacerbation, and essential hypertension, benign. M.A. Exh. 5, at 21. The physician ordered SN visits twice a week for one week, seven times a week for eight weeks, twice a week for one week, plus two SN visits prn. *Id.* The nurse was to provide skilled observation and assessment services of all body systems, including reactions to medications, and endocrine status to identify changes requiring early intervention. *Id.* The nurse was also to provide skilled teaching services related to diabetes. *Id.* The nurse was to prepare and administer Humulin R 100 units/ml on a sliding scale at noon for blood sugar (BS) 150-200 mg/dl (2 units), 201-250 mg/dl (4 units), 251-300 mg/dl (6 units), 301-350 mg/dl (8 units), 351-400 mg/dl (10 units), and notify the physician for BS greater than 401 mg/dl. *Id.* This set of records contains one home health POC for certification period August 8, 2008, through October 6, 2008, which does not contain the handwritten signature of the ordering physician. *Id.* at 21-23.

Visit note reports in these folders are almost all computer generated and indicate 60 visits to the beneficiary during this certification period. M.A. Exh. 5, at 316-20. While these clinical records state that the beneficiary is homebound and cannot leave home without considerable and taxing effort, an entry on a Client Coordinator Note Report, dated September 18, 2008, states "PT REQUEST TO BE SEEN IN THE EARLY AM INSTEAD OF AT NOON D/T PT WAS GOING OUT OF TOWN TO GO VISIT A FAMILY MEMBER. MD NOTIFIED AND AGREED." *Id.* at 326. An excerpt from a patient information record indicates that the beneficiary is ambulatory with assistance and that the beneficiary had an exacerbation of her primary diagnosis (diabetes with ophthalmic manifestations) on June 3, 2008. *Id.* at 321.

October 7, 2008-December 5, 2008 (M.A. Exh. 6)

The home health POC for certification period October 7, 2008, through December 5, 2008, indicates principal diagnosis diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled (ICD-9-CM code 250.52), with other pertinent diagnoses unchanged from the prior certification period. M.A. Exh. 6, at 22. The physician ordered SN visits five time a week for one week, seven times a week for seven weeks, six times a week for one week, plus two SN visits prn. *Id.* The nurse was to provide SN observation and assessment of all body systems,

including reactions to medications, and endocrine status to identify changes requiring early intervention. *Id.* The nurse was also "to perform fingerstick for capillary blood glucose level per glucometer [each] visit." *Id.* The nurse was further going to prepare and administer Humulin R 100 units/ml on a sliding scale at noon, consistent with previous orders. *Id.* at 22-23. This set of records contains one home health POC for certification period October 7, 2008, through December 5, 2008, which contains a handwritten signature of the ordering physician on the first page which differs from the physician's signature on pages two and three and differs from the handwritten date next to the signature. *Id.*

Visit notes in these folders are almost all computer generated, are substantially similar, and indicate that the appellant provided 60 visits during this certification period. *See* M.A. Exh. 6, at 297-301. The records state that the beneficiary is homebound and cannot leave home without considerable and taxing effort, but an entry on a Client Coordination Note Report, dated November 23, 2008, states "Missed Visit Notification," with reason for the missed visit "PATIENT NOT HOME." *Id.* at 307.

Beneficiary Interview (BI) - August 19, 2009 (M.A. Exh. 6A)

The record contains a contractor form for the BI, with interview date August 19, 2009. M.A. Exh. 6A, Exh. 3, at 1-13. The form indicates that the interview lasted approximately twenty-five minutes and that the beneficiary was not homebound during the dates of services and was not currently homebound. *Id.* at 1. Highlighted instructions state "NOTE: Questions should be asked in relation to the period of review." *Id.*

In relevant part, the BI indicates that, at the time of the interview, the beneficiary was sitting on the porch in the shade and rocking. M.A. Exh. 6A, Exh. 3, at 1. When asked whether the appellant had given her a folder, the beneficiary "went into house & retrieved folder - step up 6 inches OK - no problem." *Id.* Handwritten entries indicates that the agency visited each day on August 15, 16, 17, 18, and 19 to give insulin injections. *Id.* The beneficiary's folder, however, showed that no injection was given on August 15, 16, 17, and 18, while 2 units were given on August 19. *Id.* Notes indicate that the beneficiary's niece was at her home in the morning, while her daughter was present "all others." *Id.* at 2. The interviewer checked a box indicating that the beneficiary is and was able to leave her home and went to church if someone took her, although she did

not need a cane, walker, or wheelchair. *Id.* She stated that her son drove her to the physician every two months and she could get in and out of the car "OK." *Id.* Another entry states that the beneficiary was alert and oriented times three and "sitting in chair walked around room unassisted." *Id.* at 4.

The BI states that the beneficiary received insulin on a sliding scale, is and was not able to check blood sugar levels because "I can't" and "scared," but also provides that the agency did not attempt to instruct the beneficiary or her caregiver. M.A. Exh. 6A, Exh. 3, at 5. The form also states that the beneficiary is and was unable to self-administer insulin because "afraid". *Id.* at 6. An "aide" stated that the agency "never attempted to teach. Has fear when questioned about giving shot." *Id.* The beneficiary "wears glasses" and "sees fine." *Id.* at 8. The beneficiary did not have pain that interfered with movement, did not have a skin lesion or open wound, and did not get short of breath. *Id.* at 9. The beneficiary is documented as not requiring assistance in dressing, bathing, toileting, transferring, an ambulating. *Id.* at 11-12.

Conclusion

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service. The appellant argues that the record demonstrates that the beneficiary was homebound because documents demonstrate that the beneficiary had pain, "skin lesions are ambiguous, and the skilled nursing documented assessment of age spots each visit," the beneficiary required assistance with ADLs, and the beneficiary required assistance in leaving the home. Exh. MAC-1, at 9-10. These arguments are insufficient to reverse the ALJ's determination.

In the initial certification period and the certification period prior to the dates of service, the beneficiary requested changes to home health visit schedules so that she could leave the home and take care of her father and leave town to visit a family member. During the certification period under review, the record reflects that the beneficiary was not home at the time of a scheduled visit. The BI interview was conducted approximately nine months after the dates of service, while the beneficiary still received home health visits. The BI form documents the beneficiary's responses that she was not homebound during the dates of service and also that she was not homebound at the time of the interview. The interviewer also observed the beneficiary get up from a seated position and go into the house, without

any apparent problem, to retrieve clinical records. The beneficiary also reported no difficulty with ADLs, including ambulation. The beneficiary further reported leaving the home for church services and doctor visits without apparent difficulty or assistive devices. The record does not support that the beneficiary was homebound during the dates of service. The beneficiary was therefore not eligible for the home health benefit during that time.

Because the beneficiary was not homebound and thus did not qualify for the home health benefit, the Council need not also consider whether the services were medically reasonable and necessary in order to affirm the ALJ's denial of coverage. Nonetheless, the Council is inclined to agree with the ALJ that the beneficiary did not require the skilled services of a nurse during the dates of service. The beneficiary received either daily or twice daily SN visits for approximately two and a half years, initially for observation and assessment services related to disease process and, more recently, for blood sugar checks and intermittent insulin injections based on a sliding scale. Other than conclusory statements in computer-generated clinical records, the appellant points to no entries indicating that the agency attempted to teach the beneficiary, the beneficiary's niece, or the beneficiary's daughter how to check the beneficiary's blood sugar or to provide insulin injections as needed. The appellant has not met its burden of proof that the beneficiary required skilled services.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

2. Beneficiary M.B. (ALJ #4) (10/01/08-11/29/08): The ALJ issued an unfavorable decision for services billed under codes G0151 (PT) and G0154 (SN). Dec. at 63-64. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 65. The decision reflects SOC date August 18, 2005, and lists multiple diagnoses. *Id.* at 63-64. The POC for the dates of service states that the beneficiary was homebound and orders SN observation and assessment, Vitamin B-12 injections, and PT services. *Id.* at 64. The ALJ also reviewed visit notes, a Physical Therapy Evaluation and Treatment Plan (PT Plan), the BI (August 19, 2009), and hearing testimony. *Id.* at 64-65. The ALJ determined that the PT Plan established that the beneficiary was ambulatory and independent in many ADLs, including "her ability to perform

rolls, scoots, self feed, sitting over edge, getting in and out of bed, getting in and out of a wheelchair, toileting, getting in and out of shower/tub, bathing, self grooming, self dressing, wheelchair independent, walking in all directions and on all surfaces, climbing stairs, and car transfers." *Id.* at 65. The ALJ determined that the record did not support that the beneficiary was unable to leave home or that leaving home required a considerable and taxing effort. *Id.* The ALJ found that the skilled services were not covered because the beneficiary was not homebound.

The appellant argues that a physical therapist evaluation differs from a nurse's evaluation in completing the OASIS (Outcome and Assessment Information Set), because a nurse focuses on the safety of a patient's activities. Exh. MAC-1, at 12. The appellant also argues that merely because the beneficiary may be documented in the PT Plan as independent in activities does not also mean that the beneficiary is not homebound. *Id.* The appellant points out that the PT Plan also states that the beneficiary has fall risks, osteoporosis, surgery and limitations in the left shoulder, and abnormal posture. *Id.* at 13. The appellant also states that the beneficiary was "walking with better swing," needed "minimal cues" for proper gait, and required supervision. *Id.* The beneficiary summarizes that the beneficiary's problems included weakness, limited range of motion, impaired balance, and impaired endurance. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The appellant's argument concerning the degree of care with which physical therapists and nurses complete clinical records is speculative and entirely unpersuasive. As the ALJ pointed out, the PT Plan, dated October 2, 2008, reflects medical diagnoses osteoarthrosis, status post left rotator cuff reconstruction, and rehab diagnosis pain and limited motion to the left shoulder. M.B. Exh. 6, at 65. While the PT Plan does state that the beneficiary is a fall risk, it also states, as the ALJ noted, that the beneficiary was independent or required minimal assistance with virtually all ADLs. *Id.* at 67. There is nothing in the gait analysis which indicates that the beneficiary was unable to leave the home. *Id.* at 68. Both short-term and long-term goals pertain to the left shoulder, with one entry for "improve gait quality to increase swing/BOSx80%." *Id.* The first PT progress note, dated October 6, 2008, has entries showing the beneficiary required no

assistive device, stand by assistance, and minimal instruction for gait. *Id.* at 71. The therapist discharged the beneficiary from PT on November 28, 2008. *Id.* at 119. The claim file also documents that the beneficiary was not at home for scheduled home health visits on October 27, 2008, and November 29, 2008. *Id.* at 128, 130.

The BI indicates that the interviewers found that the beneficiary was not at home, but was "playing bingo" in a day care center. M.B. Exh. 6A, Exh. 3, at 1. The beneficiary "walked unassisted over to treatment room & talked w us." *Id.* The BI form contains a check indicating that the beneficiary was able to leave the home, but required assistance getting in and out of a car due because of knee pain. *Id.* at 2.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

3. Beneficiary J.B. (ALJ #5) (02/22/07-04/04/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 66-68. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 67. The decision indicates SOC date July 7, 2004, with multiple diagnoses. *Id.* at 66. The POC for the dates of service state that the beneficiary was homebound and provided orders for SN observation and assessment, instruction, and "perform glucometer" as needed. *Id.* The ALJ also reviewed visit notes, the BI (August 19, 2009), and hearing testimony. *Id.* at 66-67. The BI indicated that the beneficiary was able to walk outdoors in her yard, could leave home although she did not need to do so, left the home for medical appointments, and used a cane/walker, while the medical record indicated that she "visited Mexico" during the dates of service. *Id.* at 67.

The appellant does not contest the ALJ's findings, but argues that merely because a person can walk in their yard does not mean that they are not homebound. Exh. MAC-1, at 13. The appellant also argues that the BI was conducted over two and a half years after the date of service and is incomplete. *Id.* The appellant further argues that the record does not reflect how many times the beneficiary left home for medical appointments and explains that the only reference to Mexico "is a communication note dated 2/25/17 [sic.]" *Id.* at 14. According to this note, the beneficiary went to Mexico for medical treatment. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, the date of the note concerning the Mexico trip is February 19, 2007, not February 25, 2017. J.B. Exh. 6, at 56. The note provides that the beneficiary experienced flu symptoms, an upper respiratory infection, and hyperglycemia on January 3, 2007 and "went to doctor in Mexico who gave multiple meds." *Id.* An appointment was then scheduled with the treating physician (for appellant's services), after which the patient was "advised not to go to multiple MDs." *Id.* The record contains a Client Coordination Note Report, dated January 3, 2007, which states that the beneficiary had begun to experience flu-like symptoms, "she went to see a Dr. in Mexico two days ago, an injection @ MD office, med for pain and antibiotics were given." J.B. Exh. 5, at 73. The note states that no new orders or medications could be given, as the beneficiary needed to see the physician first, but "Pt refused to go see MD." *Id.*

The BI also states that the beneficiary was not homebound during the dates of service and at the time of the interview. J.B. Exh. 6A, Exh. 3, at 1. The beneficiary was sitting in an easy chair, lived alone, was able to leave her home, and walked around her yard. *Id.* at 1-2. The appellant provided a van to take her to physician appointments, and the beneficiary "tried day care but did not like it. Sitting all day. She prefers to walk around some." *Id.* at 2, 4. The BI indicates that the beneficiary took oral medication for diabetes and there was "no insulin." *Id.* at 1.

The appellant bears the burden of proving that the beneficiary meets eligibility and coverage requirements for home health services. While the appellant correctly points out that the BI is dated more than two years after the dates of service, the Council agrees with the ALJ that the record does not support that it required a considerable and taxing effort for the beneficiary to leave the home during the period at issue. The record also does not support that the beneficiary was homebound at the time of the interview.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

4. Beneficiary M.C. (ALJ #7) (08/07/06-10/05/06): The ALJ issued an unfavorable decision for services billed under codes

G0151 (PT) and G0154 (SN). Dec. at 70-72. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 72. The decision reflects SOC date December 10, 2005, and lists multiple diagnoses. *Id.* at 70. The POC for the dates of service state that the beneficiary was homebound and provided orders for SN for observation and assessment, instruction, and "administer B12." *Id.* at 70. The ALJ also reviewed physician orders, visit notes, an outpatient PT evaluation (August 7, 2006), a 60 day summary (October 2, 2006), the BI (August 18, 2009), and hearing testimony. *Id.* at 71-72. The BI indicated that the beneficiary could leave home with assistance. *Id.* at 72. The ALJ also noted that the PT evaluation occurred outside the beneficiary's home, and "the Beneficiary ambulated into the clinic without [a] device." *Id.*

The appellant argues that the BI was conducted almost three years after the dates of service, is incomplete, and is unreliable. Exh. MAC-1, at 15. The appellant also contends that leaving the home for grocery shopping or medical care does not mean the patient is not homebound. *Id.* The appellant points out that the BI does not document the frequency of absences from the home and it is unclear whether the BI refers to homebound status during the dates of service or at the time of the interview. *Id.* The appellant then discusses how the OASIS (August 2, 2006), the POC, and nurse notes document that the beneficiary is homebound. *Id.* at 15-16. The appellant argues that the services were skilled, as the nurse provided two B-12 injections, there were multiple medication changes, and the appellant was instructed on blood sugar fluctuations and osteoarthritis. *Id.* The appellant also points to one date in which the beneficiary had elevated blood pressure of 180/70 "and blood pressure noted to be 132/80 and patient complained of headache and sore throat." *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The ALJ correctly noted that the evaluation by an outpatient PT clinic, dated August 7, 2006, states that the beneficiary ambulated into the clinic without an assistive device. M.C. Exh. 6, at 76. A second PT evaluation, dated September 6, 2006, repeats that the beneficiary ambulated into the clinic without a device. *Id.* at 102. Both PT evaluations, and the supporting documentation, state that the PT services are needed to address problems with the beneficiary's right shoulder, following right shoulder surgery. *Id.* at 76, 102. Shoulder Treatment & Exercise Logs, from August 7, 2006,

through October 5, 2006, indicate that the beneficiary exercised on a recumbent bicycle, did static pushups, and performed wall slide and wall pulley therapeutic exercises, with total exercise time of approximately one hour each session. *Id.* at 101, 126, 130. In Daily Treatment Records for the same period, there were no services ordered to increase function in gait, balance, endurance, or safety. *Id.* at 78-132, *passim*. While the BI occurred significantly after the dates of service, the contemporaneous clinical documentation indicates that the beneficiary was ambulatory and able to participate in multiple exercises calling for balance and strength. The appellant has not met its burden of proving that it required considerable and taxing effort for the beneficiary to leave home during the dates of service.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

5. Beneficiary E.C.1 (ALJ #10) (04/06/07-06/04/07): The ALJ issued a partially favorable decision for services billed during the dates of service. Dec. at 76-78. The ALJ determined that the beneficiary was homebound, but that the documentation did not support that there had been any effort to teach the beneficiary or a caregiver how to administer daily Forteo injections or "why another form of treatment was not used in place of Forteo injections." *Id.* at 77. The ALJ thus determined that the appellant failed to establish medical necessity for the SN services. *Id.* The ALJ also found, however, that SN instructions related to medicine changes on April 9, 2007, and April 20, 2007, were covered by Medicare. *Id.* at 78, *citing* MBPM Ch. 7, § 40.1.2.3.

The appellant first argues that the beneficiary met homebound requirements. Exh. MAC-1, at 17-18. (As the ALJ found that this beneficiary was homebound, the Council does not address this argument.) The appellant also argues that skilled services were required for the beneficiary's "medical need for daily subcutaneous injections of forteo." *Id.* at 18. The appellant points to "exacerbations" of senile osteoporosis on August 2, 2006, refers to constipation documented on February 1, 2007, and February 22, 2007, mentions new orders for medication changes on April 9, 2007, and April 20, 2007, then states that a Client Coordination Report, dated May 31, 2007, documents "no willing/available caregiver to perform task and patient with

poor vision, manual dexterity and aversion to needles." *Id.*, *see* E.C.1 Exh. 5, at 370.

The Council finds no basis in the appellant's contentions for determining that the daily Forteo injections meet skilled care requirements. The OASIS indicates SOC date October 13, 2005, and provides that the beneficiary was referred to home health services for knowledge deficits related to the disease process and new treatment of Forteo injections for osteoporosis. E.C.1 Exh.3, at 2. The OASIS also indicates that there is no caregiver available to prepare and administer (p/a) daily injections. *Id.* However, the OASIS also indicates that the beneficiary resided in her owned or rented residence with another family member. *Id.* at 3-4. The OASIS further indicates that the beneficiary received assistance from relatives, friends, or neighbors living outside the home, a person residing in the home (who was not agency staff), and paid help. *Id.* at 4. The primary caregiver is identified as "paid help," who provided assistance "several times during day" with ADLS, Instrumental ADLs (IADLs), and other services. *Id.* A Client Information Report (print date March 26, 2012) indicates that the beneficiary "sometimes stays with daughter" and, on March 16, 2006, relocated to live with another family member. E.C.1 Exh. 5, at 383-85. This document contains multiple references to the beneficiary not being at home or being out of the service area when the appellant arrived. *Id.* at 383-98, *passim.*

The Council agrees with the ALJ that, other than brief and conclusory statement in computer-generated clinical records, there is no documentation in the record that the appellant attempted to instruct the beneficiary, the paid caregiver, a family member, or anyone else to administer daily Forteo injections during the dates of service or for approximately a year and a half before that. *See* MBPM Ch. 7, §§ 40.1.2.3, 40.1.2.4.A. The appellant has not met its burden of proof that the beneficiary required skilled services. The Council agrees that the beneficiary did not require skilled care during the dates of service and the home health services are not covered by Medicare. (The Council does not disturb the ALJ's partially favorable determinations for two dates of service.)

6. Beneficiary A.C. (ALJ #12) (05/13/08-07/11/08): The ALJ issued an unfavorable decision for services billed during the dates of service. Dec. at 81-82. The ALJ noted that the BI indicated that the beneficiary was homebound, but found that the twice daily insulin injections did not meet skilled care

requirements. *Id.* at 82. The ALJ found that, although the beneficiary required assistance with diabetic management "and her daughter worked outside the home," there was no documentation of any attempts to teach the beneficiary how to check her own blood sugar levels or to self-administer medication. *Id., citing* MBPM Ch. 7, § 40.1.2.4. The ALJ also found no documentation of any attempts to identify a willing and able caregiver to assist. *Id.*

The appellant first argues that the services should be covered because "this beneficiary meets criteria for homebound status . . . ." Exh. MAC-1, at 18-19 (citations omitted). The appellant also argues that the beneficiary required SN observation and assessment services due to "redness and dependent edema to left lower extremity and fluctuating blood sugars." *Id.* at 19. The appellant then reviews certain clinical information from May 13, 2008, through July 11, 2008, which, in relevant part, resulted in no new orders by the physician and no change to the beneficiary's insulin regimen. *Id.* at 19-21. The appellant refers to SN teaching on the diabetic condition and "exacerbation" of diabetes and osteoarthritis reflected on the POC. *Id.* at 20.

The Council need not consider the appellant's homebound argument, as the ALJ denied coverage based on the lack of skilled care, not homebound status. The appellant also does not challenge the ALJ's findings that daily insulin injections did not constitute skilled care, and the Council therefore summarily affirms those coverage denials. The Council also finds no basis in the appellant's multiple references to the record as supporting that the beneficiary required SN observation and assessment services or instruction. Generally, skilled observation and assessment services are reasonable and necessary "when the likelihood of a change in a patient's condition requires skilled nursing personally to identify and evaluate the patient's need for possible modification of treatment or initial of additional medical procedures *until the patient's treatment regimen is essentially stabilized.*" MBPM Ch. 7, § 40.1.2 (emphasis supplied). Skilled observation and assessment may also be covered when, in part, a beneficiary was admitted to care and "there was a reasonable potential of a complication or further acute episode . . . ." *Id.* The appellant points to nothing in the record which indicates that SN services were required to manage the beneficiary's overall condition during the dates of service. The initial POC reflects SOC date May 24, 2006. A.C. Exh. 3, at 42. The appellant offers no explanation

why this beneficiary continued to require SN observation, management, and instruction services approximately two years after the SOC date. The Council finds that the beneficiary did not require skilled care during the dates of service, and the home health services are not covered by Medicare.

7. Beneficiary E.C.2. (ALJ #13) (09/11/06-11/09/06): The ALJ issued an unfavorable decision for services billed during the dates of service. Dec. at 82-85. The ALJ found that the beneficiary was homebound, but that the beneficiary did not require skilled PT services. *Id.* at 84-85, *citing* MBPM Ch. 15, § 220.2; LCD (Local Coverage Determination) for Physical Therapy for Home Health (L282). In reaching this finding, the ALJ noted that Medicare requires that PT "must be for a condition that is expected to improve materially within a reasonable and generally predictable period of time. Maintenance therapies after the patient has achieved therapeutic goals are not reasonable and necessary." *Id.* at 85. The ALJ found that the services were not covered by Medicare. *Id.* at 85.

The appellant concedes that the ALJ stated that the PT record, dated August 18, 2006, indicates that the beneficiary "met maximum beneficiary/potential" and was thus discharged from PT. Exh. MAC-1, at 21. The appellant also argues, however, that the beneficiary required maximum assistance in various exercises, was confused, lethargic, and forgetful, and ambulated 25 feet with "noted right antalgic gait and right foot inverted." *Id.* The appellant points out that the beneficiary's strength was 2+/5 on the right side. *Id.* In summary, the appellant states that "[t]his documentation would show that although the beneficiary may have met goals one month ago, and be at his own maximum potential, this [PT] evaluation shows that patient needs therapy, and therapist feels there is potential benefit from ordered therapy services." *Id.* at 21-22.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The SOC date for this beneficiary is September 1, 2004. Dec. at 83. The beneficiary then began PT on March 16, 2006. *Id.* A PT note, dated August 18, 2006, states that the beneficiary received PT services 3wkx4wks, had a neurology consult to rule out stroke, and "has met maximum benefit/potential. D/C to care of MD." E.C.2 Exh. 5, at 69. The record also contains a verbal order, dated September 18, 2006, which states that PT services were put on hold on August 2, 2006, and resumed effective August 7, 2006, and another verbal order, dated September 21, 2006, which states that

another PT evaluation had been done and visits were scheduled. E.C.2 Exh. 6, at 23-24. However, these documents do not change or account for the PT therapist's note, dated approximately one month earlier, which states that the beneficiary had achieved maximum rehabilitation potential and was discharged from skilled PT services. The appellant points to nothing in the record to support significant deterioration in the prior level of function such that was an expectation of material improvement for this beneficiary within a reasonable and predictable period after PT was resumed, or that skilled services were necessary to maintain fucntion. The Council agrees with the ALJ that the beneficiary did not require skilled care during the dates of service and the services are not covered by Medicare.

8. Beneficiary F.D. (ALJ #14) (05/27/07-07/25/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 85-86. In relevant part, the ALJ determined that the beneficiary was not homebound, as both the BI and clinical records indicate that the beneficiary could ambulate safely with assistive devices and the beneficiary lived alone. *Id.* at 86. The decision indicates SOC date March 28, 2007, with diagnosis hypertension. *Id.* at 85. The POC for the dates of service state that the beneficiary was homebound and provided orders for SN observation and assessment, report changes, and instruct on new medications and hypertension. *Id.* The ALJ reviewed beneficiary symptoms on multiple dates, stated that the beneficiary lived alone, and reviewed the BI and hearing testimony. *Id.* at 85-86. The BI indicated that the beneficiary was "able to leave her home to go to church, the grocery store, shopping, visit friends, and . . . she does not need help to leave." *Id.* at 86.

The appellant argues that the OASIS, dated May 23, 2007, documents the beneficiary's homebound status because the beneficiary requires assistance to leave home, has dyspnea with exertion, is bladder incontinent, and is forgetful. Exh. MAC-1, at 22. The appellant also argues that the BI is unreliable, as it occurred more than two years after the dates of service. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The ALJ cited to records which indicate that the beneficiary could ambulate with an assistive device and lived alone, and to the BI to support that the beneficiary was not homebound. The BI states that the beneficiary was not homebound during the dates of service and at the time of the interview, lived in an apartment, and the

interviewer saw the beneficiary "in [the] day room." F.D. Exh. 5A, Exh. 3, at 1. During the interview and the dates of service, the BI states that the beneficiary was able to leave home without help to go to church, shopping, the grocery store, and to visit friends or relatives. *Id.* at 2. The beneficiary stated that she used a walker 40% of the time. *Id.* The BI also states: "Pt stated that during episode she was in the same medical condition as now. She stated she was able to walk around at that time without any type of assistance. Nothing medically going on with her at that time." *Id.* at 3. The interviewer also documented that the beneficiary was alert and oriented and "was in social area of apartment. Walked to her apartment without walker or cane to get folder." *Id.* at 4. The beneficiary was described as "up at lib, alert. In a hurry to catch bus to go shopping and out to lunch." *Id.* The interviewer further documented that a coordinator on staff at the apartment "sat in on interview with the patients permission." *Id.* The form indicates that a home health aide performed services including errands, light meals, and housekeeping, but no one provided that assistance when the aide was not present, as the beneficiary "lives alone." *Id.* at 6. In conclusion, the interviewer stated that the beneficiary was "hurrying to bus, appeared totally mobile. Shortened interview due to pt in a hurry to leave to go shopping and eat." *Id.* at 12. The record also contains documentation of missed visits on June 15, 2007, "due to patient not home" and on April 20, 2007, because "patient out of town with family member." F.D. Exhs. 5, at 52; 4, at 41.

While the BI occurred significantly after the dates of service, contemporaneous records, as well the BI, indicate that the beneficiary was ambulatory during the dates of service. The appellant has not met its burden of proving that it required considerable and taxing effort for the beneficiary to leave home.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

9. Beneficiary T.F. (ALJ #16) (08/29/08-10/27/08): The ALJ issued an unfavorable decision for services provided to this beneficiary. Dec. at 88-90. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound, as the BI indicated that the beneficiary "was able to leave his home to go to church, for medical care, and to

visit his friends without help." *Id.* at 90. The decision indicates SOC date January 2, 2008, and lists multiple diagnoses. *Id.* at 88. The POC for the dates of service provided orders for SN observation and assessment, medication response, and musculoskeletal and neurological statuses. *Id.* at 89. The ALJ reviewed visit notes, discussed beneficiary symptoms on multiple dates, and stated that the beneficiary required assistance with ambulation and ADLs. *Id.* at 89. The BI indicated that the beneficiary was "able to leave his home to go to church, for medical care, and to visit his friends without help." *Id.* The BI also indicated that the beneficiary "would attend medical appointments by driving himself or having someone else drive him" and that the beneficiary "uses a cane/walker or scooter/power wheelchair to get around." *Id.*

The appellant argues that lower adjudications found that these services meet coverage requirements. Exh. MAC-1, at 22-23. The appellant also argues that the BI was conducted a year after the period audited, that the beneficiary used a walker and "held onto a doorframe to turn off [a] computer" during the interview and that going to church, visiting relatives and friends, and receiving medical care do not mean that the beneficiary is not homebound. *Id.* The appellant asserts that the beneficiary's use of cane, walker, and power chair reflect difficulty leaving the home. *Id.* The appellant also argues that the beneficiary required the assistance of an aide to dress and shave. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, as the ALJ and Council conduct *de novo* reviews, and the ALJ provided notice that she would consider coverage for all claims in the sample, the appellant's argument that lower adjudications were favorable is irrelevant. Next, the BI states that the beneficiary was not homebound, did not require assistance in leaving home, and went to church, visited friends, and left home for medical care. T.F. Exh. 5A, Exh. 2, at 2. Handwritten notations indicate that the beneficiary has a power wheelchair given to him by his sister that he "used when he goes out," that he receives PT twice a week, and that an aide assists with shaving and dressing. *Id.* at 3. Elsewhere, the BI states that the beneficiary "dresses himself on days aide not here." *Id.* at 4. The BI also states: "He related that he recently drove auto to PV - Agency [illegible]. [M.] told him not to do that as he would get in trouble. Pt stated he will drive if he wants to, does drive self to visit mother in hospital." *Id.* at 4. The record also contains documentation that the beneficiary

ambulated approximately 285 feet with a rolling walker during gait training on October 1 and 2, 2008. T.F. Exh. 5, at 159, 162. The appellant documented a "missed visit" because the beneficiary was not at home on at least two occasions during the prior certification period. T.F. Exh. 4, at 255.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

10. Beneficiary M.H. (ALJ #21) (10/18/07-12/11/07): The ALJ issued an unfavorable decision for services billed during the dates of service. Dec. at 98-99. The ALJ found that the beneficiary was homebound, but that the services were not reasonable and necessary, as the physician had never assessed the beneficiary for dizziness, which was the reason given for the recertification. *Id.* at 99.

The appellant first argues that lower adjudicators issued favorable coverage determinations. Exh. MAC-1, at 24. The appellant then argues that the beneficiary was assessed (for dizziness) by a registered nurse (RN) and Licensed Vocational Nurses (LVNs). *Id.* The appellant states that a physician assessment is not required for skilled nursing monitoring and assessment and that the beneficiary also received PT "to assist with strengthening" and to decrease fall risk. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, the fact that lower adjudicators may have reached different determinations than an ALJ or the Council is not relevant to whether the ALJ or Council conducted *de novo* review, as required by regulation. Second, the SOC date for this beneficiary is December 22, 2005, with primary diagnosis coronary artery disease (CAD) with other diagnoses malaise, fatigue, muscle weakness, and difficulty walking. M.H. Exh. 3, at 1-2. The POC for certification period August 14, 2007, through October 12, 2007, almost two years later, reflects principal diagnosis "other and unspecified angina pectoris" with onset date August 6, 2007, and other pertinent diagnoses essential hypertension (benign), unspecified peripheral vascular disease, and "other malaise and fatigue." M.H. Exh. 4, at 22. The POC for the instant certification period, October 13, 2007, through December 11, 2007, reflects principal diagnosis of "dizziness and giddiness" with onset date October 8, 2007, and other pertinent diagnoses "other fall," coronary artherosclerosis, and other and unspecified angina

pectoris. M.H. Exh. 5, at 21. SN services were ordered 1wkx9wk for "assessment/observation of all body systems," responses to medication, reporting significant changes, and instructions on new medications. *Id.* SN was also to observe and assess the beneficiary cardiac system to identify any exacerbation for early intervention. *Id.* This POC bears what appears to be a physician's signature, dated November 7, 2007. A physician verbal order, dated October 23, 2007, indicates that a PT evaluation was completed and visits ordered. *Id.* at 25.

The Council agrees with the ALJ that the beneficiary did not require or receive skilled services during the dates of service. The documentation does not support that the beneficiary has a medical condition that, approximately two years after the onset of care for a different diagnosis, required skilled nursing observation and assessment services until the beneficiary's condition had stabilized or because there was "reasonable potential of a complication or further acute episode." MBPM Ch. 7, § 40.1.2. The documentation also does not support skilled PT services, as there is no expectation of material improvement with a reasonable and generally predictable period of time. LCD L282. The Council agrees that the beneficiary did not require skilled care during the dates of service and the home health services are not covered by Medicare.

11. Beneficiary R.L. (ALJ #22) (06/10/07-08/08/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 99-102. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 101. The ALJ decision reflects SOC date April 11, 2007, and lists multiple diagnoses. *Id.* at 100. The POC for the dates of service orders SN observation and assessment of all body systems, neurologic status, and medication response. *Id.* The ALJ also reviewed clinical records indicating that the drug Lexapro was added and discontinued soon after due to side effects, as well as visit notes, the BI (August 24, 2009), and hearing testimony. *Id.* at 100-01. The ALJ determined that the beneficiary was not homebound, as the beneficiary "was able to drive himself around" in 2007, including "driv[ing] himself to the barber shop 2-3 times per month and [to] visit his daughters," and that the beneficiary drove himself alone. *Id.* at 101.

The appellant argues that the BI was conducted almost two years after the dates of service, was incomplete, and was unclear on whether the questions pertained to the dates of service. Exh.

MAC-1, at 24-25. The appellant also argues that medication changes support the medical necessity of the skilled nursing observation and assessment services. *Id.* at 25.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI states that investigators interviewed the beneficiary's daughter and that the beneficiary was not homebound during the dates of service, but was homebound at the time of the interview. R.L. Exh. 5A, Exh. 3, at 1. The BI also contains the following notation: "'2 years ago he was driving himself around - driving himself to barber, he was able and did go by himself.' - per [R.V.] daughter." *Id.* Under "Are/Were you able to leave your home?", the response noted is "not now - 2 yrs ago was able to drive himself around." *Id.* at 2. The BI also clearly states that two years ago, the beneficiary drove by himself to the barbershop 2-3 times monthly and to visit his daughters. *Id.* The BI also states that the family had private pay assistance for the beneficiary and that his daughter lived next door. *Id.* at 6. The beneficiary's sister, an LVN, had recommended PT, which stopped in May or June. *Id.* at 8. The daughter stated that the beneficiary required help now, but was "much more independent 2 yrs ago. I would look out the window and his truck was gone." *Id.* at 12. The BI also states that the beneficiary did not require assistance in ambulation/locomotion with the handwritten notation "not during episode." *Id.*

Contrary to the appellant's assertions, the BI clearly accounts for the beneficiary's mobility during the dates of service, rather than at the time of the interview. The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

12. Beneficiary F.M.1 (ALJ #23) (08/15/07-10/13/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 102-03. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 103. The ALJ decision reflects SOC date February 16, 2007, and lists multiple diagnoses. *Id.* at 102. The POC for the dates of service orders SN observation and assessment of all body systems, medication response, and the musculoskeletal and cardiac systems. *Id.* The ALJ also reviewed a Client Coordination Report, as well as visit notes, the BI (August 10, 2009), and hearing testimony. *Id.* at 100-01. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary stated that "he was able to leave

his home if his wife drove him." *Id.* at 103. The ALJ determined that the record did not support that leaving home required a considerable and taxing effort. *Id.* The ALJ also found that the skilled services were not reasonable and necessary and not covered. *Id.*

The appellant argues that the BI was completed almost two years after the dates of service, clinical records indicate that the beneficiary had a diagnosis of Alzheimer's disease and was forgetful, that the ability to leave home for medical care does not negate homebound status, and that the BI was unclear on whether the questions pertained to the dates of service. Exh. MAC-1, at 26. The appellant also argues that the recertification documents reflect difficulty transferring, homebound status, dyspnea, and pain, limited range of motion, decreased strength, and bone and joint problems. *Id.* at 27.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI states that the beneficiary was not homebound during this episode and was not homebound at the time of the interview. F.M.1 Exh. 6A, Exh. 3, at 1. Diagnoses billed included osteoporosis, hypertension, Alzheimer's, dementia without behavioral disturbance, skin and prostate cancer, and increased blood pressure. *Id.* However, the BI contains a handwritten notation indicating no Alzheimer and no dementia, as stated by the beneficiary's wife. *Id.* The BI indicates that the beneficiary is 83 and "feels great!" *Id.* The BI states that the beneficiary needed his wife to drive when he left home for medical care and that he also had a walker. *Id.* at 2. The interviewer's observations included that the beneficiary was alert and oriented, with comments "very alert & able to answer all questions wife present & she drives him *everywhere*." *Id.* at 4 (emphasis supplied). The beneficiary's activity level at the time of the interview was stated as "able to walk OK." *Id.* Behavior problems were "none," his wife assisted with bathing, he needed no assistance transferring, and he "seemed to walk OK [without] assistance." *Id.* at 11-12.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

13. Beneficiary F.M.2 (ALJ #26) (08/21/06-10/19/06): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 107-08. In relevant part, the ALJ determined that the record did not support that the beneficiary

was homebound. *Id.* at 108. The ALJ decision reflects SOC date April 28, 2005, lists multiple diagnoses, and states that the beneficiary "lived alone." *Id.* at 107. The POC for the dates of service orders SN observation and assessment of all body systems, medication response, and home safety. *Id.* The ALJ also reviewed visit notes, physician orders, the BI (August 19, 2009), and hearing testimony. *Id.* at 107-08. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary lived alone, left home with help for grocery shopping and medical appointments, and "uses a treadmill." *Id.* at 108.

The appellant argues that the BI was completed three years after the dates of service, was incomplete, and did not reflect the frequency of absences from home. Exh. 1, at 27. The appellant states that the beneficiary was forgetful and had impaired vision, pain, and dyspnea with exertion. *Id.* The appellant then states that the ability to use a treadmill does not negate homebound status. *Id.* The appellant summarizes that "a review of this beneficiary's record will show that this beneficiary was homebound and the services rendered were reasonable and medically necessary." *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI contains a question mark concerning homebound status during the dates of service, but states "no" as the response for current homebound status. F.M.2 Exh. 6A, Exh. 3, at 1. The interviewers spoke with the beneficiary, her daughter, and the provider. *Id.* The beneficiary was able to leave the home "as needed" and her daughter "lives nearby." *Id.* at 2. The beneficiary left the home to go to the grocery store and for medical care, her "daughter takes her to places if she feels dizzy - with daughter uses cane." *Id.* The beneficiary also used an inhaler as needed. *Id.* She was alert and oriented and activity level at the interview was "uses treadmill occasionally." *Id.* at 4. The Admission OASIS, dated April 21, 2006, (four months before the dates of service) indicates that the beneficiary lived alone, received the assistance of family and paid caregivers multiple times daily, her cardiovascular and respiratory systems were within normal limits, she transferred with minimal assistance or with the use of an assistive device, she could go shopping with assistance, and she was alert, oriented to person and place, and was forgetful. *See* F.M.2 Exh. 5 (Part 1 of 3), at 1B-12B. The appellant does not point to any specific information in the

record to support that it required a considerable and taxing effort for the beneficiary to leave her home.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

14. Beneficiary P.M. (ALJ #28) (02/14/07-04/14/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 110-12. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 112. The ALJ decision reflects SOC date December 16, 2006, and lists multiple diagnoses. *Id.* at 111. The POC for the dates of service orders SN observation and assessment of all body systems, medication response and instruction, and significant changes. *Id.* The ALJ also reviewed visit notes, a Client Coordination Report, the BI (August 11, 2009), and hearing testimony. *Id.* at 110-12. The ALJ determined that the beneficiary was not homebound, as the beneficiary was not at risk for falls, "was able to leave her home to go out to eat and shop by bus and when using her walker," and that she missed two appointment because she was out of town. *Id.* at 112.

The appellant argues that the BI was completed one and one-half years after the dates of service, was incomplete, did not reflect whether the beneficiary required assistance to leave home 3–4 times weekly, and the OASIS documents that the beneficiary was homebound. Exh. 1, at 28. The appellant also argues that the services were skilled. *Id.* at 29.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI states that the beneficiary was not homebound during the dates of service and at the interview. P.M. Exh. 5A, Exh. 3, at 1. The BI also indicates that the beneficiary left her home 3-4 times weekly to go out to eat and shopping and that she took an assisted living facility bus when doing so. *Id.* at 2. The beneficiary lived in an assisted living facility apartment described as "very neat" and "clean," she filled her own medicine box which the nurse checked each week, she wore an adult diaper when taking the facility bus as a precaution, she required no assistance toileting or transferring, and she was able to bathe and dress herself. *Id.* at 4, 6, 9, 11. The beneficiary used a walker outside her home. *Id.* at 12. The record supports the finding that the beneficiary missed visits on February 24, 2007, and

March 31, 2007, because she was "out of town . . . for a week" and "out of town," respectively. P.M. Exh. 5A, Exh. 2, at 1, 5.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

15. Beneficiary R.M. (ALJ #29) (09/20/08-11/18/08): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 112-14. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 113-14. The ALJ decision reflects SOC date November 25, 2007, and lists multiple diagnoses. *Id.* at 112. The POC for the dates of service orders SN observation and assessment of all body systems, medication response and instruction, and significant changes. *Id.* at 112-13. The ALJ also reviewed visit notes, a Client Coordination Report, the BI (August 24, 2009), and hearing testimony. *Id.* at 113. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary left home approximately three times weekly without help to eat, shop, and for medical care. *Id.* at 114. The ALJ further determined that the beneficiary came and went as he pleased; received his first walker in the past two weeks, but did not use it; his children drove him to medical appointments; and the beneficiary was able to walk around during the interview, did not use the walker, exhibited no shortness of breath, "and appeared totally mobile with no physical limitations noted . . . ." *Id.* The beneficiary also said that he could "drive better than a teenager," but did not have a car. *Id.* The ALJ found that the beneficiary was not homebound.

The appellant argues that the BI was completed one year after the dates of service, the beneficiary was documented as forgetful, and the OASIS documents that the beneficiary was homebound. Exh. 1, at 29. The appellant also argues that the services were medically necessary. *Id.* at 30.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI states that the beneficiary was not homebound during both the dates of service and the interview. R.M. Exh. 6A, Exh. 3, at 1. The BI also states that the interviewer specifically questioned the beneficiary about the period September 2008 through November 2008, and he responded that "nothing medically different than now." *Id.* The BI indicates that the beneficiary left home on

average 3 times weekly, without assistance, to go out to eat, shop, and for medical care, and that "he can come and go as he pleases." *Id.* at 2. He received his first walker two weeks ago, but "does not use." *Id.* His son and daughter drove him to medical appointments. *Id.* The beneficiary appeared alert and oriented, was able to answer all questions, and his son and daughter-in-law were present and agreed with his responses. *Id.* at 4. The beneficiary walked to the door and table without using the walker, had no shortness of breath or apparent physical limitations, and "appeared totally mobile." *Id.* The record also indicates that, in a prior certification period, the appellant discharged the beneficiary from physical therapy on January 8, 2008, when the beneficiary could ambulate 150 feet times three. R.M. Exh. 4, at 132.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

16. Beneficiary E.P. (ALJ #33) (10/03/06-12/01/06): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 120-22. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 122. The ALJ decision reflects SOC date December 7, 2005, and lists multiple diagnoses. *Id.* at 120. The POC for the dates of service orders SN observation and assessment of all body systems, medication response and instruction, note significant changes, obtain weekly weights, and provide skilled instruction on diarrhea and prefilling medication box. *Id.* The ALJ also reviewed visit notes, physician verbal orders, a Client Coordination Report, the BI (August 24, 2009), and hearing testimony. *Id.* at 120-22. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary left home to go out with her husband, did not require help or an assistive device, could "come and go as she pleased," and went to the grocery store and visited friends. *Id.* at 121. The beneficiary's daughter took her to doctor appointments, and the beneficiary did not require assistance with transfers or ambulation. *Id.* The ALJ found that the beneficiary was not homebound. *Id.* at 122.

The appellant argues that the BI was completed almost three years after the dates of service, and clinical records indicate that the beneficiary was forgetful. Exh. 1, at 30. The appellant also argues that the ability to grocery shop and visit friends "does not negate homebound status." *Id.* at 31.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI indicates that the beneficiary was not homebound during the dates of service, but was homebound at the time of the interview. E.P. Exh. 6A, Exh. 3, at 1. The interviewer spoke with the beneficiary and her daughter, the beneficiary had been in a "nursing home" (also referred to as an assisted living home) for the past two years, and the beneficiary had lived with her daughter during the dates of service. *Id.* at 1, 6. The BI specifically discusses services provided at the time of the home health episode and is consistent with the ALJ's findings. *Id.* at 2-3. The BI states that the beneficiary began receiving insulin injections two years ago, "uses pen for insulin - can self inject." *Id.* at 4, 5. The BI also states that, "three years ago," the beneficiary did not require help bathing, toileting, transferring or ambulating, but "now uses a walker." *Id.* at 11-12.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

17. Beneficiary M.P. (ALJ #34) (11/22/06-01/20/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 122-24. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 124. The ALJ decision reflects SOC date July 25, 2006, and lists multiple diagnoses. *Id.* at 122. The POC for the dates of service orders SN observation and assessment of all body systems, medication response and instruction, note significant changes in endocrine system, perform daily "fingerstick" glucose testing, and teaching pertaining to "diet, skin care, administration of insulin, blood glucose testing," and reporting vital signs outside defined parameters. M.P. Exh. 6, at 19-20. The ALJ also reviewed visit notes, physician verbal orders, the BI (August 11, 2009), and hearing testimony. Dec. at 122-23. The ALJ determined that the beneficiary was not homebound, as the beneficiary could leave the home if someone else drove him, used a cane, and walked to church. *Id.* at 124. The ALJ also found the services were not reasonable and necessary. *Id.*

The appellant argues that the BI was completed two and a half years after the dates of service, does not state how often the beneficiary left home, and is incomplete. Exh. 1, at 31. The appellant also states that the beneficiary was forgetful, had

physical therapy (PT) which would increase his ability to ambulate, and also had pain and visual impairment. *Id.* at 31. The appellant also argues that the services were reasonable and necessary. *Id.* at 32.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI contains a question mark for homebound status during the dates of service and states that the beneficiary was not homebound during the interview. M.P. Exh. 6A, Exh. 3, at 1. The BI indicates that the beneficiary was outside and entered the home for the interview. *Id.* The BI states that the beneficiary was able to leave the home, did not require help, and went to church. *Id.* at 2. The BI also states that a son drove the beneficiary to physician appointments, and that a power wheelchair had been ordered, but was not yet delivered. *Id.* The interviewer's observations include that the beneficiary was "up and walking around without assistance - no cane or walker. Stated he walks to church," and that he had no shortness of breath (SOB). *Id.* at 4.

The record contains documentation of a missed visit during a prior episode, on August 19, 2006, because the beneficiary left for Mexico, and the family did not know when he would return. M.P. Exh. 6, at 101. On August 22, 2006, the beneficiary received PT services, which included 15 minutes on a manual pedlar exerciser and ambulating more than 1,000 feet without an assistive device, but with stand-by assistance. M.P. Exh. 4, at 85. On August 24, 2006, the beneficiary was discharged from PT ambulating 300 feet independently, and also independent with a home exercise program (HEP). *Id.* at 87. These activities occurred approximately three months prior to the dates of service.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

18A. Beneficiary J.R. (ALJ #39) (10/01/06-11/29/06): The ALJ issued an unfavorable decision for SN services in the first of two claims reviewed for this beneficiary. Dec. at 135-137. In relevant part, the ALJ found, without further discussion, that the record did not support that the beneficiary was homebound. *Id.* at 137. The ALJ decision reflects SOC date August 12, 2004, and lists multiple diagnoses and functional limitations. *Id.* at 135. The POC for the dates of service orders SN observation and assessment of all body systems,

medication response and instruction, cardiac and respiratory systems, pain control, obtain weights, and instruct on hypertension and asthma. J.R. Exh. 5, at 23-25. The ALJ also reviewed visit notes, physician orders, the BI (August 10, 2009), and hearing testimony. Dec. at 136. The ALJ stated that the beneficiary complained of knee pain and asked for a steroid injection, was at risk for falls, and had difficulty ambulating secondary to pain. *Id.* at 137. The ALJ determined that the services were not covered because the beneficiary did not meet homebound requirements and also found that the services were not reasonable and necessary. *Id.*

The appellant argues that lower adjudicators determined that the beneficiary was homebound and the services were reasonable and necessary. Exh. MAC-1, at 33-34. The appellant then repeats, without argument, ALJ statements concerning Medicare coverage of skilled nursing observation and assessment and teaching and training services. *Id.* at 34. The appellant also repeats the ALJ's statements concerning the start of care date (August 12, 2004) and the current dates of service (October 4, 2006, through November 29, 2006), and that "the services are a part of a long standing pattern of the beneficiary's condition and there has not been any attempt to change the treatment to resolve her condition requiring skilled services." *Id.* The appellant contends that there were multiple medication changes and that "skilled nursing addressed diagnoses/medications as ordered." *Id.* The appellant concludes that the claim meets Medicare coverage requirements, as found by the three lower adjudicators. *Id.* The appellant presents no specific contention on the ALJ's finding that the beneficiary was not homebound. *Id.* at 33-34.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, both the ALJ and the Council conduct review *de novo* and are not bound by prior determinations. 42 C.F.R. §§ 405.1000(d), 405.1100(c). The decisions of lower adjudicators are therefore not relevant to the Council's review. Moreover, while the initial determination was favorable, there was little discussion of homebound status, and there were no subsequent appeals for redetermination or reconsideration. ALJ Master Exh. 6, at 205-06. The ALJ gave pre-hearing notice that she would consider all sampled services as a new issue. In short, three adjudicators did not consider the claim before the ALJ. Second, the appellant is required to identify with specificity the portions of the ALJ's decision with which it disagrees and to explain, also with specificity, the bases for disagreeing with the ALJ's decision, including the

identification of specific record evidence that supports its position. 42 C.F.R. § 405.1112(b). In this case, the appellant largely repeats (in one instance, incorrectly) the ALJ's statements of legal principles concerning skilled observation, assessment, and education services. 42 C.F.R. § 409.33(a). The contentions are insufficient to identify the specific parts of the ALJ's decision with which it disagrees and the specific reasons for disagreement.

The appellant also presents no contentions at all concerning the ALJ's determination that "the Beneficiary failed to meet the criteria for home bound status . . . ." Dec. at 137. The BI, which is dated August 10, 2009, indicates that the contractor interviewed both the beneficiary and her daughter. J.R. Exh. 6A, Exh. 2, at 1. (While the interview indicates that it addresses dates of service March 24, 2008, through May 22, 2008, a second interview form for the dates of service at issue in this claim is largely blank. *Id.* at 13-24. The Council thus evaluates the completed BI for each of the two claims.)

The BI states that the beneficiary was homebound on the date of the interview and contains a question mark for the episode under evaluation. J.R. Exh. 6A, Exh. 2, at 1. The BI indicates that the beneficiary was subject to fainting spells due to a drop in blood pressure and was hospitalized in the last week. *Id.* The BI states that the beneficiary was able to leave her home and, on average, did so "maybe once in a blue moon" with "grocery store" checked as destination. *Id.* at 2. She used a wheelchair when out of the home during the last one or two years. *Id.* She states that she could have left home more often, "but chose to remain home." *Id.* Her daughter drove her to medical appointments and she had both a cane/walker and wheelchair. *Id.* The beneficiary appeared alert and oriented during the interview, was sitting in a chair, and the family used the wheelchair for safety reasons, due to the beneficiary "passing out." *Id.* at 4. The BI indicates that the beneficiary had daily knee pain that was not constant and that "interfered with . . . activity or movement." *Id.* at 9. She was short of breath "from time to time." *Id.* The beneficiary needed "some assistance" with getting to a toilet and "sometimes" required assistance in both transferring and ambulating (another person or an assistive device). *Id.* at 12.

While the BI indicates that the beneficiary used a wheelchair as a precaution against fainting spells, clinical records from the beneficiary's initial episode reflect start of care date August

12, 2004, with observation and assessment skilled nursing services ordered for hypertension (HTN) and gastro esophageal reflux disease (GERD). J.R. Exh. 3, at 63. On September 4, 2004, the beneficiary sustained a fractured pelvis from a fall secondary to "dizziness." *Id.* at 63. The physician ordered physical therapy (PT) services and, on October 8, 2004, the beneficiary ambulated 80 feet x 2 with a rolling walker and stand by assistance, tolerating the treatment well and without signs of fatigue. *Id.* at 81. During the episode prior to the dates of service, the beneficiary was absent from the home three times on September 12, 2006. J.R. Exh. 4A, at 64. During the dates of service, the beneficiary reported knee pain during each nurse visit of level 2 intensity (on an undefined scale), which was relieved by rest and over the counter medication Tylenol 500 mg. J.R. Exh. 5, at 28; *see also id.* at 36, 39-40, 43-44, 47-48, 51-52, 55-56. The Council concludes that the record does not support that the beneficiary was homebound during the dates of service, as the record does not support that it required a considerable and taxing effort to leave home.

Even if the beneficiary were homebound (and the Council finds that she was not), the appellant presents one contention for coverage, arguing that there were "frequent" medication changes and that "skilled nursing addressed diagnoses/medications as ordered." Exh. MAC-1, at 34. As noted, the beneficiary began receiving home health services with SOC date August 12, 2004, for skilled observation and assessment services related to hypertension and GERD. J.R. Exh. 3, at 2, 33-34. During the dates of service, the physician ordered skilled observation and assessment services once weekly for nine weeks, with four PRN visits, and principal diagnosis chronic obstructive pulmonary disease (COPD) and secondary diagnoses unspecified arthropathy, coronary artherosclerosis, and essential HTN benign. J.R. Exh. 5, at 23. The record for the dates of service contains one physician's verbal order, on November 10, 2006, for a new prescription of a blister pack Azithromycin to be taken over five days for an upper respiratory infection (URI). *Id.* at 26. The ALJ also states that the beneficiary began to receive the diuretic Hydrochlorothiazide on November 27, 2006. Dec. at 136; *see* J.R. Exh. 5, at 17. The ALJ correctly stated that Medicare covers skilled nursing services for observation and assessment of a patient's changing condition when the skills of a nurse "are required *to identify and evaluate* the patient's need for *modification of treatment* or for additional medical procedures *until his or her condition is stabilized.*" 42 C.F.R. § 409.33(a)(2)(emphasis supplied). Even if the beneficiary were

homebound during the dates of service (and the Council finds that she was not), the Council agrees with the ALJ that the beneficiary did not require skilled services.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

18B. Beneficiary J.R. (ALJ #40) (03/24/08-05/22/08): The ALJ issued an unfavorable decision for SN services in the second claim reviewed. Dec. at 137-39. In relevant part, the ALJ found, without further discussion, that the record did not support that the beneficiary was homebound. *Id.* at 139. The ALJ decision reflects SOC date August 12, 2004, and lists multiple diagnoses and functional limitations. *Id.* at 137. The POC for the dates of service orders SN observation and assessment of body systems, medication response and instruction, gastrointestinal (GI), cardiac, and respiratory systems, osteoarthritis, HTN, and bronchitis, skin issues, and cardiac complications. J.R. Exh. 6, at 21-23. The POC also orders weekly B-12 injections intramuscular (IM). *Id.* at 22. The ALJ reviewed visit notes, physician orders, the BI (August 10, 2009), and hearing testimony. Dec. at 136. The ALJ then stated, in relevant part, that the physician had ordered Norvasc, Flonase Nasal, potassium chloride, and Synthroid added to the beneficiary's medications and discontinued Levoxyl and Nasonex. *Id.* at 138. The ALJ concluded that, while the beneficiary may have had medication changes during the dates of service, "this appears to be part of a long standing pattern of the Beneficiary's condition and [there] has not been an attempt to change the treatment to resolve her condition . . . ." *Id.* at 138-39. The ALJ noted that the beneficiary began care with the appellant on August 24, 2004, and the instant episode occurred approximately four years later. *Id.* at 139, *citing* 42 C.F.R. § 409.44; MBPM Ch. 7, § 40.1.2.1. The ALJ determined that the services were not covered because the beneficiary did not meet homebound requirements and the services were not reasonable and necessary. *Id.*

The appellant repeats its prior argument that lower adjudicators determined that the beneficiary was homebound and the services were reasonable and necessary. Exh. MAC-1, at 32-33. The appellant then repeats, without argument, ALJ statements concerning Medicare coverage of skilled nursing observation and assessment and teaching and training services. *Id.* at 33. The appellant also repeats the ALJ's statements concerning the start

of care date (August 12, 2004) and the current dates of service (March 24, 2008, through May 22, 2008), and her statement that "the services are a part of a long standing pattern of the beneficiary's condition and there has not been any attempt to change the treatment to resolve her condition requiring skilled services." *Id.* The appellant then argues, again, that there were multiple medication changes, that length of time receiving home health services is not relevant to coverage of the services at issue, and that "skilled nursing was needed to address the diagnoses/medications as ordered." *Id.* The appellant concludes that the claim meets Medicare coverage requirements, as found by the three lower adjudicators. *Id.* The appellant presents no specific contention addressing the ALJ's finding that the beneficiary was not homebound. *Id.* at 32-33.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, as noted in the previous discussion for this beneficiary, *supra,* both the ALJ and the Council conduct review *de novo* and are not bound by prior determinations. 42 C.F.R. §§ 405.1000(d), 405.1100(c). Second, the appellant does not identify with the required specificity those portions of the ALJ's findings with which it disagrees and the specific bases for disagreement. 42 C.F.R. § 405.1112(b). The appellant again presents no contentions concerning the determination that the beneficiary was not homebound during the dates of service. Dec. at 139.

The Council incorporates its prior discussion of the BI, dated August 10, 2009, into this analysis. *See discussion* Beneficiary J.R., #18A (ALJ #39), *supra;* J.R. Exh. 6A, Exh. 2, at 1-12. For reasons set forth in that discussion, the Council concludes that the record does not support that the beneficiary was homebound during these dates of service. The record does not support that it required a considerable and taxing effort for the beneficiary to leave home.

Even if the beneficiary were homebound (and the Council finds that she was not), the appellant presents one contention for coverage, arguing that there were "frequent" medication changes, length of services is irrelevant to coverage, and that "skilled nursing addressed diagnoses/medications as ordered." Exh. MAC-1, at 34. As noted, the beneficiary began receiving home health services with SOC date August 12, 2004, for skilled observation and assessment services related to hypertension and GERD. J.R. Exh. 3, at 2, 33-34. During the dates of service, the physician ordered skilled observation and assessment

services once weekly for eight weeks, with six PRN visits, for principal diagnosis essential hypertension, benign, and secondary diagnoses congestive heart failure (CHF), unspecified, chronic bronchitis with acute exacerbation, and pernicious anemia. J.R. Exh. 6, at 21-22. The physician also ordered Vitamin B-12 1000 mcg injections "every week IM next due week of 3/23/08." *Id.* at 22. The record also contains two physician's verbal orders, the first increasing the number of SN visits weekly to assess blood pressure with a change in blood pressure medication and the second for SN observation and assessment for medication changes that added potassium chloride, Flonase, and Synthroid. *Id.* at 24-25. The ALJ correctly stated that Medicare covers skilled nursing services for observation and assessment of a patient's changing condition when the skills of a nurse "are required *to identify and evaluate* the patient's need for *modification of treatment* or for additional medical procedures *until his or her condition is stabilized.*" 42 C.F.R. § 409.33(a)(2)(emphasis supplied). Even if the beneficiary were homebound during the dates of service (and the Council finds that she was not), the Council agrees with the ALJ that the beneficiary did not require skilled services during the dates of service. Medication changes alone, without more, do not support coverage of SN observation and assessment services.

Finally, the Council notes that the POC reflects weekly Vitamin B-12 injections. J.R. Exh. 6, at 22; *compare* J.R. Exh. 4B, at 19-20 (POC for 01/24/08-03/23/08). The physician ordered weekly injections of Vitamin B-12 1000 mcg 2 ML, with start date February 12, 2008. J.R. Exh. 4B, at 23. A Client Coordination Note Report, dated March 22, 2008, states that the beneficiary "continues to need Vitamin B12 IM Q week x 6 months." *Id.* at 55. The appellant raised no contentions concerning the B-12 injections as a skilled service. CMS authority states that, for beneficiaries with diagnoses including pernicious anemia, Medicare covers Vitamin B-12 injections from 100mcg-1000 mcg "no more frequently than once monthly [as] reasonable and necessary dosage schedule for maintenance treatment. More frequent injections would be appropriate in the initial or acute phase of the disease until it has been determined through laboratory tests that the patient can be sustained on a maintenance dose." MBPM Ch. 7, § 40.1.2.4.A.2. The record contains no laboratory documents supporting weekly B-12 injections.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

19. Beneficiary B.S. (ALJ #41) (09/24/08-11/22/08): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 139-41. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 141. The ALJ decision reflects SOC date February 7, 2006, and lists multiple diagnoses. *Id.* at 139. The POC for the dates of service orders SN services generally once weekly every other week, plus four PRN visits, for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, instruct on monocytosis, observation and assessment of cardiac system and atrial fibrillation, venipuncture, monitor thromboembolic risk, cardiac complications, and "assessment of potential fracture, hematoma, abrasion or hemorrhage." B.S. Exh. 6, at 19-20. The ALJ also reviewed visit notes, the BI (August 13, 2009), and hearing testimony. *Id.* at 140-41. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary could leave home without help to attend church, the grocery store, the ranch, and for medical care. *Id.* at 140. During the BI, the interviewer observed the beneficiary moving around well, twice answering a telephone across the room, and standing during the interview. *Id.* The beneficiary reported driving himself around. *Id.* The ALJ also found the services were not reasonable and necessary. *Id.* at 140-41.

The appellant argues that the BI was completed more than a year after the dates of service, clinical records indicate the beneficiary is forgetful, the record does not state how often the beneficiary left home, the BI is incomplete, and it is unclear whether the BI refers to the beneficiary's condition during the dates of service or at the time of the interview. Exh. 1, at 35. The appellant also states that the OASIS documents the beneficiary's homebound status and the services were medically necessary because frequency was reduced to every other week, 5 visits were provided, and the nurse instructed on atrial fibrillation (afib) on three occasions. *Id.* at 35-36. The appellant concludes that the beneficiary was homebound and the services reasonable and necessary.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI specifically indicates that the beneficiary was not homebound during the dates of service, as well as at the time of the interview. B.S. Exh. 6A, Exh. 3, at 1. The BI states that the contractor was initially

unable to contact the beneficiary at home, as the beneficiary and his wife were then at their ranch, approximately 20 miles away. *Id.* The beneficiary was able to leave home, did not require assistance in doing so, and stated that he left home to go to church, the grocery store, shopping, and for medical care and that he also went "to the ranch on a regular basis." *Id.* at 2. The beneficiary or his daughter drove him to medical appointments, and he did not have any durable medical equipment (DME). *Id.* He appeared alert and oriented, was "moving around great," "answered phone across the room twice," and "stood during interview." *Id.* at 4. The beneficiary needed blood drawn for laboratory work once a month, and the home health nurse also provided assessment, although the beneficiary said that no teaching ever occurred. *Id.* The BI specifically addresses the dates of service, and the beneficiary stated that his condition was the same then as now, that he was not homebound. *Id.* The beneficiary's wife also stated that they shopped at Wal-Mart, the beneficiary drove himself around, and the interviewer documented "no limitations on activity noted." *Id.* The beneficiary also did not need no assistance in transferring or ambulation. *Id.* at 12.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

20. Beneficiary M.S.1 (ALJ #42) (09/09/06-11/07/06): The ALJ issued a partially favorable decision for home health services billed under codes G0154 (SN) and G0151 (PT). Dec. at 141-44. The ALJ found that the beneficiary was homebound and the SN services **were covered**, as the beneficiary was unable to monitor her own blood sugar levels and the nurse was required "to perform a fingerstick and glucometer prn." *Id.* at 144. The ALJ also found, however, that the PT services **were not covered** because clinical notes "do not contain an objective status or prior level of function." *Id.*

The appellant first argues that SN services should be covered due to SN observation and assessment and teaching services. Exh. MAC-1, at 36. The appellant also states, without argument, that a PT evaluation was conducted on September 11, 2006, PT was provided for 8 visits, and the beneficiary was discharged on October 10, 2006, "due to reached goals/maximum benefit." *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The ALJ found the beneficiary was

homebound and, contrary to the appellant's contentions, the SN services **were covered** by Medicare. The ALJ also found the PT services **were not covered**, because records did not establish objective findings or a prior level of function. Dec. at 144. The appellant does not identify any specific error in the ALJ's analysis or point to any specific record evidence to support coverage of the PT services. The Council finds no basis for changing the ALJ's decision.

21. Beneficiary M.S.2 (ALJ #43) (06/05/07-08/03/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 144-47. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 146. The ALJ decision reflects SOC date February 10, 2006, and lists multiple diagnoses. *Id.* at 144-45.

The POC for the dates of service orders SN services once weekly for nine weeks, plus two PRN visits, for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medications, observation and assessment of cardiac system with prn visits for cardiac complications, and other observation and teaching services. M.S.2 Exh. 6, at 22-24. The ALJ also reviewed visit notes, client coordination note reports, physician orders, the BI (August 18, 2009), and hearing testimony. Dec. at 145-46. The ALJ determined that the beneficiary was not homebound, despite medical records indicating functional limitations and an assistive device, because the BI indicated that the beneficiary could leave home to go to the grocery store and for medical care, although another person needed to drive. *Id.* at 146. The BI indicated that the beneficiary did not have an assistive device (cane, walker or wheelchair) and "was observed sitting on her sofa, getting up out of a chair, and walking to another room without any taxing effort." *Id.* The ALJ also found the services were not reasonable and necessary. *Id.* at 146-47.

The appellant argues that the BI was completed almost two years after the dates of service, the record does not state how often the beneficiary left home, the BI is incomplete, and the ability to move around in the home does not reflect homebound status. Exh. MAC-1, at 37. The appellant also states that the services were reasonable and necessary because of multiple medication changes. *Id.* at 37-38.

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. The BI specifically indicates that the beneficiary was not homebound during the dates of service, as well as at the time of the interview. M.S.2. Exh. 6A, Exh. 3, at 1. The beneficiary was sitting on a couch when the interviewers arrived, arose, and walked into the other room to retrieve medical information. *Id.* The BI also states that the beneficiary left home for the grocery store and medical care, and her daughter drove her to medical appointments. *Id.* at 2. She had no cane, walker, or wheelchair, and the BI states "no taxing effort to leave home." *Id.* at 2-3.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

22. Beneficiary A.S. (ALJ #44) (11/19/06-01/17/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 147-49. In relevant part, the ALJ stated that the SN services were not covered because the beneficiary was not homebound. *Id.* at 149. The ALJ decision reflects SOC date September 30, 2004, and lists multiple diagnoses. *Id.* at 147. The POC for the dates of service orders SN services once weekly for nine weeks for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, pain control, arthropathy, and endocrine system, perform glucometer when beneficiary or caregiver unable, and observation and assessment of genitourinary system with instruction on urinary incontinence. A.S. Exh. 6, at 22-23. The ALJ also reviewed visit notes, physician orders, the BI (August 11, 2009), and hearing testimony. *Id.* at 148. The ALJ determined that the services were not reasonable and necessary, as they "appear[ed] to be a part of a long standing pattern" without attempts to change treatment supporting skilled intervention, and they were "not covered as the Beneficiary failed to meet the criteria for homebound status." *Id.* at 148-49.

The appellant repeats ALJ findings that skilled observation and assessment are not covered when indications are part of a longstanding pattern and there have been no changes in treatment requiring skilled intervention. Exh. MAC-1, at 38. The appellant then argues that "there [were] multiple medication changes" during the prior and instant home health episodes, including Lidoderm patches and Sulindac (a non-steroidal anti-

inflammatory). *Id.* at 38-39. The appellant argues that "[p]ain was an issue with this patient" and is documented in the record. *Id.* at 39. The appellant asserts that the record supports that the beneficiary was homebound and the services are covered. *Id.*

The Council agrees with the appellant that the record supports that the beneficiary was homebound during the dates of service. First, the BI itself states that the beneficiary was homebound, during both the dates of service and the interview. A.S. Exh. 6A, Exh. 3, at 1. The beneficiary left home twice a week to go to the drug store and for medical care and required assistance from her daughter to walk or to be driven in a car. *Id.* at 2. The beneficiary reported daily pain "from neck down," was short of breath walking more than 20 feet, "esp. when it is hot," and was bladder incontinent. *Id.* at 9. The beneficiary required assistance dressing, bathing, and toileting. *Id.* at 11-12. While stating that she did not need assistance to ambulate, she reported "knee hurts." *Id.* at 12. The recertification, dated November 14, 2006, states that the beneficiary is homebound because she had difficulty with transferring and ambulation, could not leave home without assistance, and leaving home required a significant and taxing effort. A.S. Exh. 6, at 1. The Council finds that the beneficiary was homebound during the dates of service and reverses the ALJ on that issue.

The Council agrees with the ALJ, however, that the record does not support that the services met skilled care requirements. As noted, Medicare covers skilled observation and assessment services, in part, when professional skills "are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition *is stabilized.*" 42 C.F.R. § 409.33(a)(2)(emphasis supplied). Patient education (teaching) services are covered when professional skilled are "necessary to teach a patient self-maintenance." 42 C.F.R. § 409.33(a)(3). The appellant contends that the beneficiary required skilled care due to multiple medication changes, including pain management through the Lidoderm patch and non-steroidal anti-inflammatory agent Sulindac. Exh. MAC-1, at 39. However, the SOC Outcome and Assessment Information Set (OASIS), dated September 30, 2004, indicates that the beneficiary required physical therapy (PT), had a herniated disc, and also complained of "pain to lumbar area." A.S. Exh. 4, at 2. The recertification, dated November 14, 2006, states that the beneficiary reported daily pain that interfered with activity and movement. A.S. Exh. 6, at 2. The same recertification also reports that the beneficiary ambulates

safely with an assistive device or another person, transfers with minimal assistance with an assistive device or another person, and toilets with minimal assistance. *Id.* at 5. As the ALJ noted, the dates of service are approximately two years after the start of care. Skilled nursing services were not required to identify and evaluate treatment options in response to a changing condition. The Council finds that the services are not covered by Medicare.

The Council finds that the beneficiary was homebound during the dates of service and reverses the ALJ's decision on that issue. The Council agrees with the ALJ that the services are not covered by Medicare.

23. Beneficiary M.S.3 (ALJ #45) (10/30/07-12/28/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 149-51. In relevant part, the ALJ stated that the SN services were not covered because the beneficiary was not homebound. *Id.* at 151. The ALJ decision reflects SOC date March 19, 2004, and lists multiple diagnoses. *Id.* at 149. The POC for the dates of service orders SN services generally every other week for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, observation and assessment of cardiac system, musculoskeletal status, and endocrine system, and instruction on dyslipidemia and cholecystitis. M.S. Exh. 6, at 24-25. The ALJ also reviewed visit notes, physician orders, the BI (August 14, 2009), and hearing testimony. *Id.* at 148. The ALJ determined that the services were not reasonable and necessary, as they "appear[ed] to be a part of a long standing pattern" without attempts to change treatment that supported skilled intervention. *Id.* at 151. The ALJ found that the beneficiary began receiving home health services over three and a half years before, there was "no documentation of any recent exacerbations or hospitalizations," and there did not appear to be any attempts to change treatment in response to the beneficiary's condition. *Id.* The ALJ found that the services were "not covered as the Beneficiary failed to meet the criteria for homebound status." *Id.*

The appellant argues that the beneficiary received the new medication "requip" on December 12, 2007, and received instruction on hyperlipidemia and laboratory testing. Exh. MAC-1, at 39. The appellant also points out that SN visits were reduced for this episode. *Id.* The appellant concludes that the

beneficiary was homebound and that the services were reasonable and necessary. *Id.*

The Council agrees with the appellant that the record supports that the beneficiary was homebound during the dates of service. First, the BI itself states that the beneficiary was homebound, both during the dates of service and at the time of the interview. M.S. Exh. 6A, Exh. 3, at 1. The beneficiary left home three times weekly "just for dialysis" and her daughter drove. *Id.* at 2. The BI contains a checkmark in the box for "church." *Id.* The beneficiary needed assistance leaving home and used a walker and a wheelchair as she was "afraid she will fall." *Id.* While the beneficiary walked without a cane or walker, she was "slow moving." *Id.* at 4. The BI states that it "appears it would be a taxing effort for her to leave the house. [L]egs hurt." *Id.* The recertification, dated October 26, 2007, states that the beneficiary is homebound because she had shortness of breath, ambulation difficulties, and was not able to leave home without assistance. M.S. Exh. 6, at 1. The Council finds that the beneficiary was homebound during the dates of service and reverses the ALJ on that issue.

The Council agrees with the ALJ, however, that the record does not support that the beneficiary required skilled care during the dates of service. As noted, Medicare covers skilled observation and assessment services, in part, when professional skills "are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition *is stabilized.*" 42 C.F.R. § 409.33(a)(2)(emphasis supplied). Patient education (teaching) services are covered when professional skilled services are "necessary to teach a patient self-maintenance." 42 C.F.R. § 409.33(a)(3). The appellant contends that the beneficiary required skilled care due to the addition of the drug "Requip," an anti-Parkinson's drug, on December 12, 2007, and instruction on hyperlipidemia. Exh. MAC-1, at 39. While the Client Medication Report supports that Requip was added to the beneficiary's medication regiment on December 12, 2007, the subsequent nurse visit note, dated December 19, 2007, makes no reference to any observation and assessment or instruction for this medicine. A.S. Exh. 6, at 19, 41-44. There were also no material changes in the POCs from the prior episode to the episode under review. *Compare* M.S. Exh. 5, at 24-26 *with* M.S. Exh. 6, at 24-26. The Council notes that Welchol, an anti-cholesterol medication, was added to the beneficiary's medication regimen on September 13, 2007, to be given twice

daily by mouth. M.S. Exhs. 5, at 22; 6, at 19. This occurred before the dates of service, and there is no indication that the beneficiary or her daughter required further instruction on oral anti-cholesterol medication for "self-maintenance." 42 C.F.R. § 409.33(a)(3); *see also* MBPM Ch. 7, § 40.1.2.3 (teaching and training activities). As the ALJ noted, the dates of service are approximately three and a half years after the start of care, and the services are not required to identify and evaluate treatment options in response to the beneficiary's changing condition or to instruct the beneficiary. The services are not covered by Medicare.

The Council finds that the beneficiary was homebound during the dates of service and reverses the ALJ's decision on that issue. The Council agrees with the ALJ that the services are not covered by Medicare.

24. Beneficiary O.T. (ALJ #47) (12/10/06-02/07/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 154-55. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 155. The ALJ decision reflects SOC date October 11, 2006, and lists multiple diagnoses. *Id.* at 154. The POC for the dates of service orders SN services once weekly for nine weeks, plus two PRN visits, for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, observation and assessment of respiratory system, and teaching services for asthma, endocrine status, and glucometer reading. O.T. Exh. 5, at 30-32. The ALJ also reviewed visit notes, client coordination note reports, physician orders, the BI (August 10, 2009), and hearing testimony. Dec. at 154-55. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary could leave his home to go to church, the grocery store, the drug store, or medical care; his son drove him or he would take the bus; and during the interview, the beneficiary "was able to get up and down and walk without difficulty." *Id.* at 155. The ALJ found the services not covered because the beneficiary was not homebound. *Id.*

The appellant argues that the BI was completed almost three years after the dates of service, the record does not state how often the beneficiary left home, the BI is incomplete, and the OASIS indicates that the beneficiary is forgetful. Exh. MAC-1, at 40. The appellant also contends, without citation, that

"according to Medicare *regulations*, going to church, grocery store, drug store and medical care does not invalidate homebound status." *Id.* (emphasis supplied). The appellant then contends that the beneficiary "has and uses a cane and knee brace." *Id.* The appellant maintains that the beneficiary's mobility during the interview is inconsistent with documentation from the dates of service, which show "difficulty transferring, ambulating," using a cane, and "assistance with ADLs." *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. Contrary to the appellant's argument, Medicare *regulations* concerning homebound status provide that a Medicare beneficiary "must be confined to the home . . . ." 42 C.F.R. § 409.42(a); *see also* Section 1814(a) of the Act. CMS manual authority interprets this as meaning that "there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort." MBPM Ch. 20, § 30.1.1 (10-01-03). Individuals may leave the home infrequently, for relatively short durations, or to receive health care treatment without negating homebound status. *Id.* Examples of such health care treatment include attending "adult day centers to receive medical care," ongoing outpatient kidney dialysis, or chemotherapy or radiation therapy. *Id.* Attending religious services is considered to be an absence that is infrequent or of short duration and thus does not negate homebound status. These examples do not include going to the grocery store or drug store for general shopping.

The CMS manual discusses other examples that "do not indicate that the patient has the capacity to obtain the health care provided outside rather than inside the home." These examples include patients paralyzed from a stroke who are confined to a wheelchair or use crutches to walk; a blind or senile person requiring assistance from another person; a person with loss of the use of upper extremities who cannot open doors or use handrails; a person in the late stages of ALS or a neurodegenerative disability; a patient recently discharged from inpatient hospitalization with post-surgery weakness and pain; a person with "heart disease of such severity that they must avoid all stress and physical activity;" and a patient with a psychiatric disorder that manifests itself in a refusal to leave home or when leaving home would be considered unsafe. *Id.* CMS also states, however, that an "aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age would not be considered confined to the home for

purposes of receiving home health services unless they meet one of the above conditions." *Id.*

The BI states that the beneficiary was not homebound during the dates of service, as well as at the time of the interview. O.T. Exh. 5A, Exh. 3, at 19. The contractor interviewed the beneficiary and his wife, and the beneficiary "walked out to fence - interviewed in carport - went into kitchen to retrieve documents." *Id.* Boxes are checked showing that the beneficiary could leave home and went to church, the grocery store, the drug store, and for medical care. *Id.* at 20. When going to medical appointments, the beneficiary either took a bus or was driven by his son. *Id.* The BI states that the beneficiary had a cane/ walker and a knee brace, but the comments state that he "does not use/need cane or knee brace." *Id.* Handwritten notes state that the beneficiary performed his own blood sugar checks and was "totally mobile." *Id.* at 21. The beneficiary was alert and oriented and was observed "sitting, getting up and down, walking without difficulty." *Id.* at 22.

The Council's review does not support that the beneficiary had a "normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort." MBPM Ch. 20, § 30.1.1. The Council's review also does not support that the beneficiary's absences from the home were infrequent or of such short duration as to fall within permissible exceptions to homebound status. The beneficiary's condition also does not appear consistent with those contemplated by the manual. Finally, the recertification, dated December 5, 2006, indicates that the beneficiary required minimal assistance with ADLs and ambulation. O.T. Exh. 5, at 4-5.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

25. Beneficiary L.V. (ALJ #48) (07/19/07-09/16/07): The ALJ issued an unfavorable decision for services billed under codes G0154 (SN) and G0155 (social worker). Dec. at 155-57. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 157. The ALJ decision reflects SOC date July 19, 2007, and lists multiple diagnoses. *Id.* at 156. The ALJ also noted functional limitations that included mental retardation. *Id.* The POC for the dates of service orders SN services once weekly for nine weeks for observation and assessment of all body systems,

medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, observation and assessment of cardiac system, and other observation and instruction services for the coronary artery and gastrointestinal systems, genitourinary status, and "prefill pillbox [every] week." L.V. Exh. 4, at 25-27. The ALJ also reviewed client coordination note reports, physician orders, the BI (August 10, 2009), and hearing testimony. Dec. at 156-57. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary left his home on a daily basis to attend adult daycare. *Id.* at 157. The ALJ stated that, although the beneficiary had Down's Syndrome, he was able to leave by himself as long as transportation was provided. *Id.* The ALJ found the services not covered because the beneficiary was not homebound. *Id.* at 157.

The appellant argues that the BI was completed almost two years after the dates of service, and the beneficiary's responses cannot be given much weight as he has Down's Syndrome, memory deficit, and mental retardation. Exh. MAC-1, at 41. The appellant also argues that adult day care attendance does not negate homebound status, and the beneficiary used transportation to leave home. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, the contractor interviewed the beneficiary's mother and sister-in-law, not the beneficiary. L.V. Exh. 4A, Exh. 3, at 14. The beneficiary's cognitive abilities are therefore irrelevant to the evidentiary value of interview responses. Second, CMS provides that homebound status is not negated, generally, when a patient leaves the home on an infrequent basis, for short periods of time, or because of "the need to receive health care treatment." MBPM Ch. 20, § 30.1.1. One example of the need to receive health care treatment includes "attendance at adult day centers to receive medical care." *Id.* The appellant points to no evidence in the record, and the Council's review does not find any evidence, to support that the beneficiary left the home daily to attend an adult day center in order to receive medical care.

The BI states that the beneficiary was not homebound during the dates of service or the interview. L.V. Exh. 4A, Exh. 3, at 14. The adult day care center took the beneficiary to medical appointments, and his sister-in-law met him there. *Id.* He used transportation to get to the adult day care center. *Id.* at 15. He did not have any DME, including a cane/walker or wheelchair.

Id. The beneficiary was able to walk fine, and the day care transportation dropped him off at home in mid-afternoon. *Id.* at 17. His sister-in-law was also his home health aide and visited him daily for personal care and housekeeping. *Id.* at 19. He was not short of breath, was not incontinent, and did not require assistance dressing the upper body, bathing, toileting, transferring, or ambulating. *Id.* at 23-26.

The record indicates that the beneficiary sustained a fall from a chair on July 16, 2007. L.V. Exh. 4, at 105. The beneficiary was then "dismissed" by another home health agency on July 17, 2007. *Id.* at 105, 98, 9. The admission assessment, dated July 29, 2007, provides that the beneficiary lived in a home with a family member, his daughter, who assisted with ADLs. *Id.* at 3, 105. The beneficiary had no observable impairment in the ability "to hear and understand complex or detailed instructions and extended or abstract conversation." *Id.* at 4. He had minimal difficulty expressing ideas and needs, required some assistance and direction in specific situations that involved shifting attention or significant stimulation, but exhibited no behavior problems. *Id.* at 4, 6. He was short of breath on moderate exertion and had limited range of motion because of obesity. *Id.* at 5, 7. He required no assistance dressing his upper body or his lower body, if clothes were laid out for him. *Id.* at 7. He required minimal assistance transferring and ambulating. *Id.*

The appellant's contentions provide no basis for concluding that the beneficiary had a "normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort." MBPM Ch. 20, § 30.1.1. The Council's review does not indicate that all of the beneficiary's daily absences from the home were to obtain medical treatment. The appellant has not met its burden of proving that the beneficiary was homebound during the dates of service.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

26. Beneficiary M.Y. (ALJ #51) (03/06/07-05/04/07): The ALJ issued an unfavorable decision for services billed under code G0154 (SN). Dec. at 163-65. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 164. The ALJ decision reflects SOC date May 10, 2006, and lists multiple diagnoses. *Id.* at 163. The

POC for the dates of service orders SN services five times weekly for one week; seven times weekly for seven weeks; six times weekly for one week; and six PRN visits for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, observation and assessment of endocrine system, glucometer "fingerstick" blood sugar readings each visit, injection of insulin (Lantus 34 units) every morning, and other observation and teaching services for respiration and cardiac systems and urinary incontinence. M.Y. Exh. 6, at 20-21. The ALJ also reviewed visit notes, physician orders, the BI (August 10, 2009), and hearing testimony. Dec. at 163-64. The ALJ determined that the beneficiary was not homebound, as the BI indicated that the beneficiary was able to leave home to go to church, the grocery store, the drug store, and for medical care, with her daughter driving her. *Id.* at 164. The ALJ also found that, at the interview, the beneficiary walked to the front door with no assistance and no taxing effort, she was babysitting an infant at that time, and she got out of her chair several times to assist the infant. *Id.* The ALJ concluded that the beneficiary was not homebound. *Id.* The ALJ also found that the services were not covered. *Id.* at 164-65.

The appellant argues that the BI was completed two and a half years after the dates of service, was incomplete, and did not indicate the frequency or purposes of absences. Exh. MAC-1, at 41. The appellant also argues that the OASIS assessment and nurse notes document that the beneficiary's memory is unreliable and clinical documentation should be given more weight. *Id.* at 41-42. The appellant points out that the interview also says that the beneficiary used a cane and states that the record indicates that the beneficiary used a multi-wheeled walker. *Id.* at 42. The appellant challenges the ALJ's statement that the beneficiary required someone else to drive her as a "clear error of fact" and being the interviewer's opinion. *Id.* The appellant argues that there were multiple medication changes during the dates of service, along with insulin injections. *Id.* The appellant asserts that medication changes show exacerbation of diabetes and "potential diagnoses." *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, the contractor interviewed both the 61 year old beneficiary *and* her daughter, and the BI indicates that those interviewed appeared alert and oriented. M.Y. Exh. 6A, Exh. 3, at 10, 13. The recertification, dated

March 2, 2007, states that the beneficiary is alert and oriented times three, is "forgetful," and has no abnormal neurological findings. M.Y. Exh. 6, at 6. The SOC OASIS, dated May 10, 2006, shows no observable impairment in hearing, communicating, comprehension, or cognition. M.Y. Exh. 4, at 4, 6-7. The Council finds no basis for giving less weight to the BI, based on the appellant's lone assertion that the beneficiary was "forgetful." Second, the BI states that the beneficiary has a cane/walker, but elsewhere states that the beneficiary walks with no assistive device and her daughter drives her when she leaves home. M.Y. Exh. 6A, Exh. 3, at 10-13. Consistent with this statement, the Council notes a missed visit from the prior episode, dated February 13, 2007, when an employee wrote:

> Miss visit for visit of 2-13-07. Pt. not home, left with her daughter . . . early in AM and her daughter will perform glucometer check and prep/administer her AM insulin of Lantus 34 units SQ Q AM. SN called [physician] office spoke w [employee]. Notified of miss visit. Will inform MD.

M.Y. Exh. 5, at 240.

The BI states that the beneficiary was not homebound during the dates of service or at the time of the interview. M.Y. Exh. 6A, Exh. 3, at 10. The BI in multiple spots indicates that the beneficiary ambulated without assistance, was able to leave her home, and left her home to go to church, the grocery store, the drug store, and for medical care. *Id.* at 10, 11, 13.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

27. Beneficiary C.Z. (ALJ #53) (04/12/07-06/10/07): The ALJ issued an unfavorable decision for the services provided. Dec. at 167-68. In relevant part, the ALJ determined that the record did not support that the beneficiary was homebound. *Id.* at 168. The ALJ decision reflects SOC date June 16, 2006, and lists diagnoses "pure hypercholesterolemia and hypertension." *Id.* at 167. The POC for the dates of service orders SN services once weekly for eight weeks, with four PRN visits, for observation and assessment of all body systems, medication response and instruction, report significant changes or unfavorable responses, instruct on new medication, observation and assessment of cardiac system, instruction on dyslipidemia,

and up to two PRN visits for "potential skin tear, fracture, hematoma, abrasion or hemorrhage." C.Z. Exh. 5, at 20-21. The ALJ also reviewed visit notes, physician orders, the BI (August 12, 2009), and hearing testimony. Dec. at 167-68. The ALJ determined that the beneficiary was not homebound, as she left her home to attend an adult day center "where she would play bingo and socialize." *Id.* at 168. The ALJ noted that, while the beneficiary required that someone drive her, "she was able to leave unsupervised and was even able to walk to the van with her walker." *Id.* The ALJ concluded that the services were not covered because the beneficiary was not homebound. *Id.* at 168.

The appellant argues that the BI was completed two and a half years after the dates of service, the beneficiary was homebound during both the interview and the dates of service, the beneficiary required assistance leaving the home, and "Adult Day Care is an accepted part of homebound" definition. Exh. MAC-1, at 43. The appellant also argues that the record does not support that the beneficiary was able to leave home unsupervised and she required a walker. *Id.* The appellant further argues that the beneficiary required assistance bathing, was in chronic pain, was short of breath, and tired easily. *Id.*

The Council finds no basis in the appellant's contentions for reversing the ALJ's decision. First, the appellant misstates the role of adult day centers in determining homebound status. CMS has stated that absences from the home to attend adult day centers *to receive medical care* do not negate homebound status. MBPM Ch. 20, § 30.1.1 (emphasis supplied). The BI indicates that the beneficiary's activities at the day center included bingo and socializing, purposes that do not fall within the exception. C.Z. Exh. 5A, at 16. Second, as the ALJ recognized, a van took the beneficiary to adult day care, and she used a walker to leave her home and get to the van. *Id.* The reason given for not leaving home otherwise was "no transportation." *Id.* The beneficiary had a walker, but was "able to walk out of house w/o walker to the fence to request a business card." *Id.* at 16, 18. While the daughter helped with dressing and bathing, the beneficiary required no assistance toileting or transferring and was "able to walk on her own but does use a walker.' *Id.* at 25-26.

The beneficiary was initially admitted to home health services following a total knee replacement (TKR) on June 1, 2006, after which she received rehabilitation services and was discharged on June 14, 2006. C.A. Exh. 3, at 122. The beneficiary was

referred to the appellant for a PT evaluation on June 16, 2006, was assessed for PT on June 19, 2006, ambulated 100 feet without an assistive device and contact guard assistance (CGA) on July 11, 2006, and was discharged from PT on July 24, 2006, ambulating with a rolling walker and with "goals achieved." *Id.* at 98, 75, 90, 96. The patient was again referred to PT on August 14, 2006, for evaluation and treatment. *Id.* at 100. The recertification, dated April 11, 2007, indicates that the beneficiary had daily knee pain at a level of 2 (on an undefined scale), alleviated with rest, over the counter medication (Buprofen), and immobility. C.Z. Exh. 5, at 2-3. She was able to bathe independently with the use of a device, could toilet independently, and transferred and ambulated with minimal assistance or the use of an assistive device. *Id.* at 5-6. A Client Coordination Note Report, dated May 16, 2007, states that the beneficiary was going to visit the physician's office and denied shortness of breath or difficulty breathing. *Id.* at 76. On May 23, 2007, the physician provided new orders for PT evaluation and treatment. *Id.* at 22-23.

The Council agrees with the ALJ that the beneficiary was not homebound during the dates of service and the services are not covered by Medicare.

V. The Appellant is Liable for Non-Covered Services and the Extrapolated Overpayment under Sections 1879 and 1870 of the Act

The ALJ found the appellant liable for the non-covered services under section 1879 of the Act and not entitled to waiver of overpayment under section 1870 of the Act. Dec. at 49-50, 54. The appellant presents no contentions on these findings. Exh. MAC-1. The Council therefore affirms that the appellant is liable for the non-covered services and extrapolated overpayment under sections 1879 and 1870 of the Act.

(Continued on next page.)

DECISION

The Council finds that the statistical sample and extrapolation are valid. The Council reverses the ALJ's homebound findings for Beneficiaries A.S. and M.S.3. The Council otherwise affirms the ALJ's determinations that the services are not covered, that the appellant is liable under section 1879 of the Act, and that recovery of the overpayment is not waived under section 1870. The ALJ's decision is modified consistent with the above analysis.

MEDICARE APPEALS COUNCIL

Clausen J. Krzywicki
Administrative Appeals Judge

Constance B. Tobias, Chair
Departmental Appeals Board

Date: JUN 5 2015

ATTACHMENT
Palm Valley Health Care, Inc.
ALJ Appeal 1-716318652
Docket M-12-3079

	Beneficiary (ALJ No.)	HICN	Dates of Service
1.	M.A. (2)	XXX-XX-2935A	10/07/08 - 12/05/08
2.	M.B. (4)	XXX-XX-1023A	10/01/08 - 11/29/08
3.	J.B. (5)	XXX-XX-9222A	02/22/07 - 04/04/07
4.	M.C. (7)	XXX-XX-2311A	08/07/06 - 10/05/06
5.	E.C.1 (10)	XXX-XX-0208A	04/06/07 - 06/04/07
6.	A.C. (12)	XXX-XX-1980B	05/13/08 - 07/11/08
7.	E.C.2 (13)	XXX-XX-8592A	09/11/06 - 11/09/06
8.	F.D. (14)	XXX-XX-4827B	05/27/07 - 07/25/07
9.	T.F. (16)	XXX-XX-5319A	08/29/08 - 10/27/08
10.	M.H. (21)	XXX-XX-0377B	10/18/07 - 12/11/07
11.	R.L. (22)	XXX-XX-5283A	06/10/07 - 08/08/07
12.	F.M.1 (23)	XXX-XX-6002A	08/15/07 - 10/13/07
13.	F.M.2 (26)	XXX-XX-5924B	08/21/06 - 10/19/06
14.	P.M. (28)	XXX-XX-6385B	02/14/07 - 04/14/07
15.	R.M. (29)	XXX-XX-2343A	09/20/08 - 11/18/08
16.	E.P. (33)	XXX-XX-8722B	10/03/06 - 12/01/06
17.	M.P. (34)	XXX-XX-0910A	11/22/06 - 01/20/07
18.	J.R. (39)	XXX-XX-5417A	10/01/06 - 11/29/06
	J.R. (40)	XXX-XX-5417A	03/24/08 - 05/22/08
19.	B.S. (41)	XXX-XX-3604A	09/24/08 - 11/22/08
20.	M.S.1 (42)	XXX-XX-2824B	09/09/06 - 11/07/06
21.	M.S.2 (43)	XXX-XX-2166A	06/05/07 - 08/03/07
22.	A.S. (44)	XXX-XX-5973A	11/19/06 - 01/17/07
23.	M.S.3 (45)	XXX-XX-5932B	10/30/07 - 12/28/07
24.	O.T. (47)	XXX-XX-9652A	12/10/06 - 02/07/07
25.	L.V. (48)	XXX-XX-8114C1	07/19/07 - 09/16/07
26.	M.Y. (51)	XXX-XX-1899A	03/06/07 - 05/04/07
27.	C.Z. (53)	XXX-XX-8676A	04/12/07 - 06/10/07

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Southern Field Office
100 S.E. 2nd St.
Suite 1660
Miami, Florida 33131
1-866-622.0382
305-415.7400

June 8, 2012
Regular Mail

Radhika Vemula, Esq.
Kennedy Attorneys & Counselor at Law
12222 Merritt Drive, Suite 1750
Dallas, TX 75251

Subject: Notice of Decision for Appeal No.: 1-716318652

Dear Ms. Vemula:

Enclosed is the decision of the Administrative Law Judge (ALJ) on your Medicare appeal. Please carefully review this notice and the attached decision.

Your Appeal Rights

If you do not agree with the ALJ's decision, you may appeal the decision by filing a Request for Review with the Medicare Appeals Council (MAC). Other parties to your appeal and, in some cases, the Centers for Medicare and Medicaid Services (CMS) or its contractors may also ask the MAC to review the ALJ's decision. If no party appeals and the MAC does not review the ALJ's decision at the request of CMS or its contractors, the ALJ's decision is binding on all parties. You will have no right to ask a federal court to review the ALJ's decision.

If you are not already represented, you may appoint an attorney or other person to represent you in any filings or proceedings before the MAC. Legal aid groups may provide legal services at no charge. If you or your representative have not completed or submitted an Appointment of Representative form, please contact the MAC for further instructions or to obtain a form.

What to Include in Your Request for Review

Your appeal must identify the parts of the ALJ's decision with which you disagree, and explain why you disagree. For example, if you believe that the ALJ's decision is inconsistent with a statute, regulation, CMS ruling, or other authority, you should explain why the decision is inconsistent with that authority.

You may submit a Request for Review with the MAC in either of the following two ways:

1. Complete and submit a Request for Review Form (DAB-101).
   Online forms at: http://www.hhs.gov/dab/DAB101.pdf
2. Submit to the MAC a written request that contains all of the following information:

   - The beneficiary's name;
   - The beneficiary's Medicare Health Insurance Claim Number (HICN);
   - The item or service in dispute;
   - The specific date(s) the item(s) or service(s) were provided;
   - The date of the ALJ decision;
   - The ALJ appeal number;
   - The parts of the ALJ's decision with which you disagree and an explanation of why you disagree; and
   - Your name and signature and/or the name and signature of your representative.

Please send a copy of the ALJ's decision with your Request for Review.

When and Where to File the Request for Review

You must submit your request to the MAC **within sixty (60) days** of receipt of this notice. The MAC will assume you received this notice five (5) days after the date indicated at the top of this notice unless you show that you received this notice at a later date. If you file your Request for Review late, you must establish that you had good cause for submitting the request late.

Your Request for Review should be mailed to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Alternatively, you may fax your request to (202) 565-0227. If you send a fax, please **do not** also mail a copy. ***You must always send a copy of your Request for Review to the other parties to your appeal.*** If you do not have the addresses of the other parties, please contact our office.

What Procedures Apply to the MAC's Review of Your Appeal

The Medicare regulations at 42 C.F.R. Part 405, Subpart I, apply to this case.

How the MAC May Respond to Your Request for Review

The MAC will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary. The MAC may change the parts of the ALJ's decision that you agree with. The MAC may adopt, change, or reverse the ALJ's decision, in whole or in part, or it may send the case back to an ALJ for further action. The MAC may also dismiss your appeal.

Where to Obtain Additional Information About the MAC

Additional information about the MAC is available on the Departmental Appeals Board's website at http://www.hhs.gov/dab/reconsiderationqic.html. You can also obtain additional information by contacting the MAC at (202) 565-0100.

Questions About the Decision

If you would like additional information concerning the attached decision, please call or write this office at: 100 S.E. 2nnd Street, Suite 1660, Miami, Florida 33131 or-1-866-622.0382.

Sincerely,

Elena Hoskins
Paralegal Specialist
Southern Field Office

Enclosures:

Form OMHA-152, Decision
Form OMHA-156, Exhibit List
Form DAB-101, Request for Review; online form at: http://www.hhs.gov/dab/DAB101.pdf

cc: Maximus QIC Part A East
3750 Monroe Avenue, Suite 701
Pittsford, NY 14534

Jeffrey Craig, Esq.
Chase Consulting, Inc.
7686 Richmond Highway, Suite 113
Alexandria, VA 22306

Lisa Garcia/Holly Pu
Health Integrity
9240 Centerville Road
Easton, MD 21601

Alex Flores
Palm Valley Health Care, Inc.
119 E. Canton
Edinburg, TX 78539

Palmetto GBA
Part A Appeals, AG-630
PO Box 100238
Columbia, SC 29202

U.S. Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Southern Region
Miami, FL

Appeal of:	**Palm Valley Health Care, Inc.**	ALJ Appeal No:	**1-716318652**
Beneficiaries:	**Multiple – 53 (see attached list)**	**Medicare Part A**	
HICN:	**Multiple – 53 (see attached list)**	Before:	**Lauren Heard** U.S. Administrative Law Judge

SUMMARY

After carefully considering the evidence and testimony in the record, a **PARTIALLY FAVORABLE** decision is entered in the appeal of Palm Valley Health Care, Inc. (Appellant). The undersigned finds Medicare payment shall be allowed for some of the claims at issue, and that the use of extrapolation is supported because the statistical methodology was valid.

STATEMENT OF THE CASE

The Appellant submitted assigned claims for home health care services on behalf of multiple Medicare Beneficiaries,[1] for dates of service ranging from July 1, 2006 through January 31, 2009 (Master File, Ex. 6, pp. 248-273). The services at issue involve the following: a physical therapist in a home health setting, each fifteen (15) minutes (HCPCS code G0151); services of a skilled nurse in a home health setting, each fifteen (15) minutes (HCPCS cod G0154); services of a clinical social worker in a home health setting, each fifteen (15) minutes (HCPCS code G0155); and services of a home health aide in a home health setting, each fifteen (15) minutes (HCPCS code G0156) (Master File, Ex. 3, p. 1). The claims were initially paid (Id.). However, Health Integrity, LLC, a Medicare Zone Program Integrity Contractor (ZPIC), subsequently reopened these claims for post payment review and determined that Medicare made payment in error (Id.). The ZPIC issued a notice of overpayment on February 18, 2010 stating that "[y]ou have received Medicare payment in error, which has resulted in an overpayment of

[1]

$12,589,185.00 for services dated July 1, 2006 through January 31, 2009 for 54 claims" (Id.). On March 19, 2010, the ZPIC again sent correspondence to the Appellant, explaining that according to 42 CFR §405.750, the Appellant was overpaid in the amount of $12,589,185.00 (Master File, Ex. 5, p. 23). The Appellant filed requests for reconsideration with the affiliated contractor with jurisdiction, Palmetto Government Benefit Administrators (PGBA) (Master File, Ex. 2, pp. 25-234). PGBA issued redetermination decisions denying Medicare coverage for most of the services, finding partially favorable for one (1) Beneficiary (Id.; Master File, Ex. 3, p. 1). On August 13, 2010, the Appellant filed requests for reconsideration with MAXIMUS Federal Services, Inc., the Medicare Qualified Independent Contract (QIC) (Master File, Ex. 1, pp. 236-263). The Appellant argued that the Beneficiaries were homebound, the services were reasonable and medically necessary, and Home Integrity did not accurately calculate the statistical sampling and extrapolation or accurately review the statistical sampling and extrapolation (Id.; Master File, Ex. 4, p. 28). On October 14, 2010, the QIC issued its decision, holding that the home health services are not covered for twenty-nine of the beneficiaries[2] and that the statistical audit by Health Integrity was consistent with the Medicare Program Integrity Manual (MPIM) and generally accepted statistical practice (Master File, Ex. 4, pp. 28-94).

On December 11, 2010, the Appellant filed a request for an ALJ hearing with a written appeal brief (Master File, Ex. 4, pp. 1-21). Regarding the twenty-nine denied claims, the Appellant argued: the claims were properly billed; the beneficiaries were in the stated conditions as the records indicated; the beneficiaries were homebound; the services were reasonable and medically necessary; and that Health Integrity did not properly reopen the claims and has not presented good cause to do so (Master File, Ex. 4, p. 5). The Appellant further argued that the overpayment was not accurately calculated (Id.). The Appellant does not believe the proper methodology was used to determine the overpayment (Master File, Ex. 4, p. 16). The Appellant stated that the sample size is not representative of the universe it is supposed to represent (Id.). The Appellant explained that the minimum sum method (MSM) was developed to generate overpayment amounts for claims that are either fully paid or fully denied (Id.). However, with the claims at issue, a partially favorable decision may be rendered (Id.). Accordingly, the Appellant argues that application of the MSM is invalid (Id.). The Appellant also believes that the MSM is invalid as the parameters for the sample and extrapolated overpayment is calculated at a 90% lower bound; however, the remaining 10% is not estimated by the methodology (Master File, Ex. 4, pp. 16-17). Therefore, the total overpayment alleged against the provider cannot be clearly verified as accurate due to the ill-defined affects from the 10% not being estimated (Master File, Ex. 4, p. 17). However, at a pre-hearing conference held on March 7, 2012, the Appellant's attorney clarified that the Appellant was not arguing that the MSM was used in this matter.

A telephonic hearing was held on April 10, 2012 through April 11, 2012. The following appeared on behalf of the Appellant: Radhika Vemula, Esq., with Kennedy Attorneys &

2

Counselors at Law; Jeffrey Witmer, Ph.D., statistical expert; George C. Cobb, Ph.D., statistical expert; Sandra Gonzalez, Nurse/Director of Nursing; Alex Escamilla, Quality Assurance Supervisor; Betsy Barrera, Nurse/Branch Manager; Erica Brown, Nurse/Branch Manager; Stephanie Flores, RN; Angelica Preza Villareal, RN; Marissa Serna, RN; Jan Spears, President and CEO of MJS Associates, an independent consulting firm; and Terri Sessions, RN, MJS Associates. The following appeared on behalf of Health Integrity: Holly Pu, statistician; and Lisa Garcia, RN, Claims Analyst. The parties and participants were sworn in and the exhibits from the Master File and each of the 53 Beneficiary files was entered into evidence without objection.

ISSUES

The issues before the ALJ are whether the Appellant has been overpaid for the home health care services on behalf of multiple Medicare Beneficiaries,[3] for dates of service ranging from July 1, 2006 through January 31, 2009, and if not, whether any Medicare payment may be made under the limitations of liability provisions of §1879 of the Act. If payment for the home health services is denied, an additional issue arises as to whether the recovery of the overpayment may be waived under §1870(b)(1)(B) of the Social Security Act. Finally, the undersigned ALJ must determine whether the statistical sampling methodology was valid.

FINDINGS OF FACT

The Appellant submitted assigned claims for home health care services on behalf of fifty-three Beneficiaries[4] for dates of service ranging from July 1, 2006 through January 31, 2009 (Master File, Ex. 6, pp. 248-273). Please see attached addendum for Beneficiary-specific fact discussions.

A telephonic hearing was held on April 10, 2012 through April 11, 2012. Ms. Vemula objected to Health Integrity's April 6, 2012 Statistical Reports, submitted on April 9, 2012, being entered into evidence less than twenty-four hours prior to the hearing. Ms. Pu testified that the Report was written mainly for her own preparation and that the Report did not contain any new information. This objection was overruled.

3

Ms. Vemula began by providing an opening statement. She argued that pursuant to the "Rule of Thumb" in the CMS Medicare Policy Benefit Manual, Pub. 100-07, Chapter 7, §20.3, a statistical extrapolation to determine whether a provider has been overpaid for a claim based on home health services cannot be used as each individual claim must be reviewed based on the Beneficiary's needs. Section 20.3 states:

> Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms is not appropriate.

Ms. Vemula then questioned Professor Cobb and Professor Witmer on their expertise, education, accomplishments, and training related to statistics in order to qualify them as experts. The undersigned ALJ accepted Professor Cobb and Professor Witmer as experts.

Professor Cobb testified that in order to analyze the statistics in this matter he used the methodology test and downstream test. He testified that Health Integrity's work contained so many errors that it could not be determined to be statistically valid. Professor Cobb first looked at the universe and stated that Health Integrity did not choose correctly as the universe was too narrow. He explained that the universe excluded underpayments and therefore the Appellant was prejudiced. The CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.3.2.1(b) states:

> The universe shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period. For some reviews, the period of review may best be defined in terms of the date(s) of service because changes in coverage policy may have occurred.

Professor Cobb next analyzed the underlying variation in the sample created. He testified that the variable being estimated is the overpayment analysis. Professor Cobb noted that the sample size was too small and that there was no probe sample. Professor Witmer also testified that there was no preliminary analysis completed for sample size and that there was no probe sample. Professor Witmer testified that Health Integrity divided the sample into two (2) strata, with a total of fifty-four claims. Professor Witmer testified that there should have been seventy-eight claims per strata, totaling one hundred and fifty-four claims. The smaller sample size results in a higher error rate. Professor Witmer testified that the sample was not representative and that it reflects the universe inappropriately.

Professor Witmer testified regarding the types of claims and explained that therapyrsuant to the clustering test shows that the sample used by Health Integrity did not represent the universe. The mean number of claims per Beneficiary for the universe was 8.43, but for the sample it was 1.02.

The standard deviation number of claims per Beneficiary for the universe was 2.90, but for the sample it was .14. Professor Witmer stated that if the sample was representative of the universe, then the values for the sample would be close to the values for the universe. However, the numbers are glaringly out of line.

Professor Witmer next testified regarding the diagnostic code test. He explained that this showed the sample was not representative of the universe by focusing on strata one. Some of the claims were denied for different amounts. Therefore, the sample used by Health Integrity was not valid. Professor Witmer testified that the sample failed in three (3) ways: first, the sample was too small; second, the sample was not representative based on the claims per Beneficiary test; third, the sample was not representative based on the diagnostic codes test. Based on the foregoing, Professor Witmer testified that there is no credibility to Health Integrity's extrapolation of the sample.

Professor Cobb also testified regarding the extrapolation. He stated that the sample was not reasonably extrapolated by Health Integrity based on two (2) tests. According to the formula consistency test, there are several ways to obtain a point estimate. This should be consistent with the sample size computation. However, the sample used "yes-no" data and the extrapolation used "continuous" amount. Therefore, the extrapolation was not valid and has no credibility. Because there is a mismatch, Health Integrity failed the formula consistency test. Professor Cobb admitted this is not as critical as other issues, but it is important. Professor Cobb next addressed the uniform error rate across the sample. This deals with the relationship between the size of the claim and rate of error. Health Integrity inflated the extrapolation amount when its computations assumed a flat 50% error rate across more than 10,000 claims. Professor Cobb testified that the 50% error rate used by Health Integrity was merely a hypothetical and therefore the point estimate has no credibility. Professor Witmer agreed that the 50% error rate was a hypothetical and noted that the actual error rate was 54%.

Professor Cobb next testified regarding the confidence interval. Professor Cobb ran a central limit theorem (CLT) compatibility test, which refers to a bell curve. The variability is the margin of error. Professor Cobb testified that the CLT compatibility test examines whether required conditions are met. In this case, the answer was no as the margin of error was incorrect. Also, the clustering made the extrapolation invalid. Therefore, the recoupment amount was wrong. Professor Cobb testified that the precision was nowhere near what was claimed. There was a 23% overall precision, which is very poor and far worse than the standard. Professor Cobb testified that there should be about 10% or better precision.

In summary, Dr. Witmer testified that Health Integrity did not use a correct sample size. Further, the error rate was wrong, and the sample was 1/3 of what was required. Finally, the claims per beneficiary test demonstrated that the sample was not representative of the universe. Professor Cobb testified that the form consistency test failed, there was major bias, the error rate distribution method used was biased, the extrapolation was invalid, the COT compatibility test failed because of clustering, and the precision test failed.

Next, Ms. Pu testified on behalf of Health Integrity. She first explained that the statistical sample was undertaken because the typical home health benefit lasts for two (2) consecutive

episodes. However, the Appellant's average was five (5) plus consecutive episodes. Health Integrity concluded that this difference warranted investigation. The benchmark was five plus (5+) sixty day episodes in about a three (3) year timeframe between 1996 and 1999. The Appellant was the highest in the state of Texas for having a pattern of continuous episodes. Over sixty percent of the Appellant's patients received five (5) plus continuous episodes.

Ms. Pu testified that the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.1.3 describes the steps for conduction a statistical sample. It states:

> The major steps in conducting statistical sampling are: (1) Selecting the provider or supplier; (2) Selecting the period to be reviewed; (3) Defining the universe, the sampling unit, and the sampling frame; (4) Designing the sampling plan and selecting the sample; (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) Estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collection of the overpayment.

Ms. Pu argued that Health Integrity complied with these steps.

Ms. Pu testified that the universe was defined as all claims from beneficiaries with five plus (5+) home health care episodes with payments between $1,000 and $6,000 billed for services rendered between July 1, 2006 and July 31, 2009. There were 10,699 claims for which the Appellant was paid a total of $26,522,686.00.

Ms. Pu next testified that the sample size was each claim. A two (2) strata sample was used with 27 claims in each stratum for a total of 54 claims in the sample. Stratum one (1) was for claims with payments between $1,000 and $3,000. Stratum two (2) was for claims with payments between $3,000 and $6,000. The 54 claims were randomly selected in such a manner that each and every claim in the universe had an equal chance of being selected. Ms. Pu testified that the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.11.1 states that generally "a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying." Ms. Pu pointed out that this section also states "that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample."

Ms. Pu further testified that in accordance with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.4.2 Health Integrity used the software statistical package RAT-STATS. Pursuant to with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.5.1, Health Integrity used the lower limit of the one-sided 90 percent confidence interval. Ms. Pu explained that this is a conservative method and works to the financial advantage of the provider.

Regarding the Appellant's argument that Health Integrity had no probe sample for error rate or variability, Ms. Pu testified that the CMS Medicare Program Integrity Manual, Pub. 100-08,

Chapter 8, §8.4.1.4 that payment error may be determined through many ways, including, but not limited to: error rate determinations by MR unit, PSC, ZPIC, or other area; probe samples; data analysis; provider/supplier history; information from law enforcement investigations; allegations of wrongdoing by current or former employees of a provider or supplier; audits or evaluations conducted by OIG. Accordingly, Ms. Pu argued that using a data analysis instead of a probe sample complies with Medicare guidelines.

Ms. Pu next addressed the Appellant's argument that the sample was not representative of the universe. She testified that pursuant to both the visual check of distribution and the statistical hypothesis testing for differences, the results both demonstrated that the sample is representative of the universe.

Regarding precision, Ms. Pu testified that Health Integrity followed all Medicare guidelines and that the precision in this case is not unusual. She explained that there is always uncertainty in sample design. Additionally, the lower bound of a 90% confidence interval accounts for lack of precision to the Appellant's advantage.

Ms. Pu testified that Health Integrity follows the CMS Medicare Program Integrity Manual regarding underpayments. She explained that if an underpayment is found on medical review, it is factored into the extrapolation.

Regarding the error rate, Ms. Pu testified that Health Integrity's 75% error rate was based on a proactive data analysis. Palm Valley was identified as the number one (1) facility for continuous episodes of home health services. The universe was closely targeted to claims with certain characteristics to insure the audit addressed whether the Appellant had been properly paid. The final actual error rate was 54%.

Dr. Cobb testified that he agreed with many of Ms. Pu's points. He testified that while Health Integrity complied with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.2 regarding the sample itself, he argued the problems arose with everything after. Regarding representation, Mr. Cobb testified that a larger sample would have worked better. By using a small sample, there were issues with clustering, etc. Mr. Cobb testified that the lower limit confidence interval proved that large +/- results in a lower recoupment amount. He also testified that the universe excluded underpayments as zero (0) paid claims were not part of the sample. He testified that there was no sampling of claims under $1,000. He argued that this is prejudicial to the Appellant.

Dr. Witmer testified that the way Health Integrity defined the universe, it was impossible for underpaid claims to be a part of the universe. He pointed out that there was a 75% presumed error rate. However the actual error rate was 54%, which demonstrates the proactive data analysis was wrong. He also testified that clustering is a big issue. There was an eight (8) to one (1) ratio that was ignored by Health Integrity.

Ms. Pu testified that her previous testimony was adequate to address the issues raised by Dr. Cobb and Dr. Witmer. Ms. Vemula had no further testimony and no closing remarks.

Please see attached addendum for Beneficiary-specific hearing testimony.

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act §1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. See, 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. Id.

To be entitled to a hearing before an ALJ, a party must meet the minimum amount in controversy requirement. 42 C.F.R. §405.1006. The amount in controversy threshold for ALJ hearing requests filed on or after January 1, 2010, is $130. 74 Fed. Reg. 48976 (September 25, 2009). The request for hearing is timely if filed within sixty days after receipt of a QIC Reconsideration. See, 42 CFR §405.1002(a)(1).

B. Scope of Review

For all appeals stemming from a QIC, the ALJ appeals process is governed by 42 CFR §§405.1000 et seq. 42 CFR § 405.1032 states, "[t]he issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in your favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify you and will consider it an issue at the hearing."

Because of the unique issues presented by a statistical overpayment case, the undersigned determined before the hearing that all of the claims in the sample would need to be reviewed. This included claims that were decided entirely favorably to the appellant at the lower levels. To ensure compliance with the regulations, the ALJ notified the appellant that all claims, including those decided favorably to the appellant at the lower levels, would be reviewed at the ALJ hearing. Such notice was given in the Notice of Hearing, which was sent to the Appellant prior to the hearing. The Notice of Hearing stated the following:

> Any part of the decision you are appealing may be reviewed, including parts which you agree with. ***When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used by the QIC, in accordance with 42 CFR 405.1064.*** If you wish to

> object to these issues, please indicate and explain your objections...in the enclosed Response to Notice of Hearing. Alternatively, you may submit your written objections at a later time, but no later than five (5) days before the date of your scheduled hearing. You must send a copy of your objections to all the parties to the appeal. The ALJ will make a decision on your objections either in writing or at the hearing." (Emphasis Added).

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005); see also, In re Atlantic Anesthesia Associates, P.C., MAC (June 2004) ("An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to §1869 of the Act. This requires de novo consideration of the facts and law.").

II. Principles of Law

A. Statutes and Regulations

1. Medicare Part B

a. Home Health Services

The Medicare program, Title XVIII of the Social Security Act (42 U.S.C. §§1395 – 1395ccc), is administered through the Centers for Medicare and Medicaid Services (CMS).

Sections 1812 and 1813 of Title XVIII of the Social Security Act establish the scope of benefits of the hospital insurance program under Medicare Part A. See also 42 C.F.R. §§ 409.1 et seq.

Section 1814(a)(2)(C) of the Act provides that "[e]xcept as provided in subsections (d) and (g) and in §1876, payment for services furnished an individual may be made only to providers of services which are eligible therefore under §1866 and only if a physician, or, in the case of services described in subparagraph (B), a physician, nurse practitioner, or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and re-certifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such re-certifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in §1861(m)(7)) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while the individual was under the care of a physician." See also 42 C.F.R. §409.41.

Section 1815(a) of the Act provides that "[n]o payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period."

Section 1832(a)(2)(A) states in relevant part:

> (a) Except as provided in subsections (b), (c), and (e), payment for services described in §1832(a)(2) furnished an individual may be made only to providers of services which are eligible therefore under §1866(a), and only if—
>
> (2) a physician, or in the case of services described in subparagraph (A), a physician enrolled under §1866(j), certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—
>
> (A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in §1861(m)(7)) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in §1861(aa)(5)) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in §1861(gg)) as authorized by State law, or a physician assistant (as defined in §1861(aa)(5)) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary.

Section 1842(a)(1)(C) of the Act authorizes carriers, "to make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part."

Section 1861(m) of the Act provides that "[t]he term 'home health services' means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed

by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home: (1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse; (2) physical or occupational therapy or speech-language pathology services; (3) medical social services under the direction of a physician; (4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary; (5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk), but excluding other drugs and biologicals) and durable medical equipment while under such a plan; (6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and (7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations." See also 42 C.F.R. §409.42 (beneficiary qualifications for coverage); §409.43 (plan of care requirements); §409.44 (skilled services requirement); §409.47 (place of service requirement); §484.18 (acceptance of patients, plan of care and medical supervision); §484.30 (skilled nursing services); §484.32 (therapy services); and §484.34 (medical social services).

Section 1861(o) of the Act provides that "[t]he term 'home health agency' means a public agency or private organization, or a subdivision of such an agency or organization, which: (1) is primarily engaged in providing skilled nursing services and other therapeutic services; (2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse; (3) maintains clinical records on all patients; (4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing; (5) has in effect an overall plan and budget that meets the requirements of subsection (z); (6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization; (7) provides the Secretary with a surety bond; and (8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program; except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law." See also 42 C.F.R. §409.42(e) (services must be furnished by a participating HHA); §484.16 (group of professional personnel); §484.20 (reporting OASIS information); §484.48 (clinical records); and §484.55 (comprehensive clinical assessment of patients).

Section 1861(s)(1) of the Act provides that "[t]he term 'medical and other health services' specifically includes physicians' services."

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See also 42 C.F.R. §411.15(k).

Section 1862(a)(21) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services where such expenses are for home health services (including medical supplies described in §1861(m)(5), but excluding durable medical equipment to the extent provided for in such section), furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency." See also 42 C.F.R. §409.49 and §424.22.

Section 1879 of the Act limits the liability of the beneficiary and providers of services if the services are found to be not medically reasonable and necessary under §1862(a)(1)(A) or care was custodial in nature under §1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered." See also 42 C.F.R. §411.404 and 42 C.F.R. §411.406.

Section 1895(a) of the Act provides that "[n]otwithstanding §1861(v), the Secretary shall provide for portions of cost reporting periods occurring on or after October 1, 2000, for payments for home health services in accordance with a prospective payment system established by the Secretary under this section." See also 42 C.F.R. § 484.200.

Section 1895(b)(1) of the Act provides that "[t]he Secretary shall establish under this subsection a prospective payment system for payment for all costs of home health services. Under the system under this subsection all services covered and paid on a reasonable cost basis under the Medicare home health benefit as of the date of the enactment of this section, including medical supplies, shall be paid for on the basis of a prospective payment amount determined under this subsection and applicable to the services involved. In implementing the system, the Secretary may provide for a transition (of not longer than four (4) years) during which a portion of such payment is based on agency-specific costs, but only if such transition does not result in aggregate payments under this title that exceed the aggregate payments that would be made if such a transition did not occur." See also 42 C.F.R.§484.205.

Section 1895(b)(2) of the Act provides that "[i]n defining a prospective payment amount under the system under this subsection, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services." See also 42 C.F.R. §484.202.

Section 1895(b)(4)(A) of the Act provides that "[t]he payment amount for a unit of home health services shall be the applicable standard prospective payment amount adjusted as follows: (i)

Case mix adjustment.—The amount shall be adjusted by an appropriate case mix adjustment factor (established under subparagraph (B); and (ii) the portion of such amount that the Secretary estimates to be attributable to wages and wage-related costs shall be adjusted for geographic differences in such costs by an area wage adjustment factor (established under subparagraph (C)) for the area in which the services are furnished or such other area as the Secretary may specify. See also 42 C.F.R. §484.205.

Section 1895(b)(4)(B) of the Act provides that "[t]he Secretary shall establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services." See also 42 C.F.R. §484.205.

Section 1895(c) of the Act provides that "[w]ith respect to home health services furnished on or after October 1, 1998, no claim for such a service may be paid under this title unless: (1) the claim has the unique identifier (provided under §1842(r)) for the physician who prescribed the services or made the certification described in §§ 1814(a)(2) or 1835(a)(2)(A); and (2) in the case of a service visit described in paragraph (1), (2), (3), or (4) of §1861(m), the claim contains a code (or codes) specified by the Secretary that identifies the length of time of the service visit, as measured in 15 minute increments." See also 42 C.F.R. §484.205.

Under 42 CFR §409.42, to qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

> (a) Confined to the home. The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.
>
> (b) Under the care of a physician. The beneficiary must be under the care of a physician who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.
>
> (c) In need of skilled services. The beneficiary must need at least one of the following skilled services as certified by a physician in accordance with the physician certification and recertification requirements for home health services under §424.22 of this chapter.
>
> > (1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in §409.32. (Also see §409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.)
> >
> > (2) Physical therapy services that meet the requirements of §409.44(c).
> >
> > (3) Speech-language pathology services that meet the requirements of §409.44(c).

> (4) Continuing occupational therapy services that meet the requirements of §409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period.
>
> (d) Under a plan of care. The beneficiary must be under a plan of care that meets the requirements for plans of care specified in §409.43.
>
> (e) By whom the services must be furnished. The home health services must be furnished by, or under arrangements made by, a participating HHA.

Pursuant to 42 CFR §409.43(b), the physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished. Section 409.43(c) instructs that for final payment, the plan of care must be signed and dated by a physician and sent to the home health agency before the claim for payment is submitted to Medicare. Further, §409.43(d) explains that when any services provided are based on a physician's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

Section 409.44(a), regarding skilled nursing services, states that a determination of whether a service requires the skill of a licensed nurse, requires that consideration be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice. If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service. However, the fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

Section 409.44(c) instructs that to be covered, physical therapy must satisfy the following criteria:

> (1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in §484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program, they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(iv) The amount, frequency, and duration of the services must be reasonable.

Section 409.45 discusses home health aide services and provides that to be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the

beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician's order must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

See also, 42 CFR 410.59 (Outpatient Occupational Therapy Services) and 42 CFR 410.60 (Outpatient Physical Therapy Services);

b. Overpayment and Statistical Sampling

Medicare law contains several provisions dealing with liability for and recovery of overpayments. Pursuant to these provisions, if a provider is without fault with respect to an overpayment he received, he is not liable for the overpayment and therefore is not responsible for refunding the amount involved.[5] When the provider is without fault, liability shifts to the beneficiary.[6] However, recovery from the beneficiary may be waived if it is determined that the beneficiary is without fault and recovery would defeat the purposes of Title II or Title XVIII of the Act.

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See also Section 1862(a)(9) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for expenses incurred for items and services where such expenses are for custodial care." See also 42 CFR §411.15(g); 42 CFR §411.15(k).

Section 1866(a)(1)(A)(i) of the Act provides that "[a]ny provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)) of the Act." See also 42 CFR §489.1 *et seq.* (setting forth the terms and limitations on provider agreements), see also 42 CFR §489.2 (providing that hospitals are providers subject to the requirements of §1866 of the Act); see also 42 CFR §489.21 (setting forth the specific limitations on charges).

[5] § 1870(b) of the Act.
[6] § 1870(a) and (b) of the Act.

Section 1870(b)(1) of the Act provides that where:

> [M]ore than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount...(2) any payment has been made under section 1814(e) to a provider of services or other person for items or services furnished an individual,-proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments—
>
> As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1817(g), and section 1841(f), shall certify (to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974) the amount of the overpayment as to which the adjustment is to be made. For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.
>
> (c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1862(a) and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the third year

> following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title. See also 42 CFR §411.28 (setting for the requirements for waiver of recovery and compromise of claims). See also, 42 CFR §405.350 (setting forth an individual's liability for payments made to providers and other persons for items or services); 42 CFR §405.351 (providing that individuals are not liable for incorrect payments); 42 CFR §405.352 (providing for adjustment of Title XVIII claims); 42 CFR §405.355 (providing that there may be no adjustment or recovery in any case where an incorrect payment has been made with respect to an individual who is "without fault" or where the adjustment or recovery would be made by decreasing payments to another person who is "without fault" . . . if such adjustment or recovery would defeat the purpose of Title II or XVIII of the Act or would be against "equity and good conscience."); 42 CFR §405.356 (providing that additional principles that should be applied in determining waiver or adjustment of recovery are found in 20 CFR §404.507-509, 20 CFR §404.510a and 20 CFR §404.512); 42 CFR §405.358 (indicating when waiver of recovery may be applied).

Section 1879 of the Act limits the liability of the beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. See also 42 CFR §411.404; 42 CFR §411.406.

Section 1893 of the Act established the Medicare Integrity Program. Pursuant to this provision, the Secretary of Health and Human Services is authorized to enter into contracts designed to strengthen the integrity of the Medicare program. Relevant to the instant case is Section 1893(h) of the Act, which created Recovery Audit Contractors (RACs). RACs receive payment under the contract only on amounts recovered from providers or correct amounts paid to providers. Payment is contingent on amounts recovered or correct amounts paid. See §1893(h)(1). Subsection (h)(4) provides that "audit and recovery activities may be conducted during a fiscal year with respect to payments made under part A or B during such fiscal year; and retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year).

Section 1893(f)(3) states:

> (3) Limitation on use of extrapolation.—A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—
>
> (A) there is a sustained or high level of payment error; or

> (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

Similarly, 42 CFR §405.926(p) instructs that actions which are not initial determinations and are not appealable under this subpart include, but are not limited to "[d]eterminations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act."

As an alternative to individualized claims adjudication, sampling has been used by government agencies as a means to determine overpayments in instances involving large numbers of beneficiaries and claims.[7] The Act provides requirements that Medicare contractors must follow when extrapolating overpayment amounts via sampling. The Act states that a Medicare contractor may not use extrapolation to determine overpayment amounts unless the Secretary determines that "...there is a sustained or high level of payment error; or documented educational intervention has failed to correct the payment error."[8] The ALJ may not review the Secretary's decision that there has been a sustained or high level of payment error.[9]

As described in §1893(f), statistical sampling may be used to accurately estimate overpayments made by the Medicare program. Statistical sampling may be used to determine a dollar amount of overpayments found through a post payment review.

B. Policy and Guidance

Title XVIII, Section §1871(a)(2) of the Act provides that national coverage decisions are binding upon ALJs. See also 42 C.F.R. § 405.1060. Section §1871(a)(2) further states that unless promulgated as a regulation by the CMS, no rule, requirement, or statement of policy, other than NCDs can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies or local coverage decisions. Also considered are the manuals issued by CMS in implementing the Medicare program.

a. Home Health Services

The CMS Medicare Program Integrity Manual, Chapter 3, §3.11, explains that "[f]or Medicare to consider coverage and payment for any item or service, the information submitted by the

---

[7] Chaves County Home Health Service v. Sullivan, 931 F.2d 914, 289 U.S. App. D.C. 276 (DC, 1991). See also, Sullivan v. Everhart, 494 U.S. 83, 110 S.Ct. 960, 964-66, 108 L.Ed.2d 72 (1990) (upholding as permissible the Secretary's construction of provisions of the Act allowing a net calculation of overpayment benefits).
[8] § 1893(f)(3); 42 U.S.C.§ 1395ddd(f)(3)
[9] Id.

supplier or provider [] must be corroborated by the documentation in the patient's medical records that Medicare coverage criteria have been met." It continues that the patient's medical records must be maintained by the physician, provider, and/or supplier and that they must be available to the contractor upon request. Moreover, sufficient documentation is required in order to confirm that an item or service was actually provided and billed at the appropriate level.

CMS General Information, Eligibility and Entitlement Manual, Publication 100-1, Chapter 4, §§10, 30, and 80, which set forth the certification and recertification requirements for home health services. In their relevant part, the Manual sections provide:

> **§30 – Certification and Recertification by Physicians for Home Health Services**
>
> Under both the hospital insurance and the supplementary medical insurance programs, no payment can be made for covered home health services that a home health agency provides unless a physician certifies that:
>
> - The home health services are because the individual is confined to his/her home and needs intermittent skilled nursing care, physical therapy and/or speech language pathology services, or continues to need occupational therapy;
>
> - A plan for furnishing such services to the individual has been established and is periodically reviewed by a physician; and
>
> - The services are or were furnished while the individual was under the care of a physician.
>
> Since the certification is closely associated with the plan of care (POC), the same physician who establishes the plan must also certify as to the necessity for home health services. Certifications must be obtained at the time the plan of care is established or as soon thereafter as possible.
>
> The attending physician signs and dates the POC/certification prior to the claim being submitted for payment; rubber stamps are not acceptable.

Also considered is the CMS Medicare Benefit Policy Manual, Publication 100-2, Chapter 7. Pursuant to §30:

> To qualify for the Medicare home health benefit, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, a Medicare beneficiary must meet the following requirements:
>
> - Be confined to the home;
> - Under the care of a physician;

- Receiving services under a plan of care established and periodically reviewed by a physician;
- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or
- Have a continuing need for occupational therapy.

For purposes of benefit eligibility, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

A patient must meet each of the criteria specified in this section. Patients who meet each of these criteria are eligible to have payment made on their behalf for services discussed in §§40 and 50.

Section 30.1 states that "a physician [must] certify in all cases that the patient is confined to his/her home. An individual does not have to be bedridden to be considered confined to the home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort." It continues:

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not

necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

Generally speaking, a patient will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of: supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists would be:

- A patient paralyzed from a stroke who is confined to a wheelchair or requires the aid of crutches in order to walk;
- A patient who is blind or senile and requires the assistance of another person in leaving their place of residence;
- A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence;
- A patient in the late stages of ALS or neurodegenerative disabilities. In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay. For example, a patient may leave the home (under the conditions described above, e.g., with severe and taxing effort, with the assistance of others) more frequently during a short period when, for example, the presence of visiting relatives provides a unique opportunity for such absences, than is normally the case. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.
- A patient who has just returned from a hospital stay involving surgery who may be suffering from resultant weakness and pain and, therefore, their actions may be restricted by their physician to certain specified and limited activities such as getting out of bed only for a specified period of time, walking stairs only once a day, etc.;
- A patient with arteriosclerotic heart disease of such severity that they must avoid all stress and physical activity; and
- A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe for the patient to leave home unattended, even if they have no physical limitations.

> The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age would not be considered confined to the home for purposes of receiving home health services unless they meet one of the above conditions.
>
> Although a patient must be confined to the home to be eligible for covered home health services, some services cannot be provided at the patient's residence because equipment is required that cannot be made available there. If the services required by an individual involve the use of such equipment, the HHA may make arrangements with a hospital, skilled nursing facility (SNF), or a rehabilitation center to provide these services on an outpatient basis. (See §50.6.) However, even in these situations, for the services to be covered as home health services the patient must be considered as confined to home; and to receive such outpatient services a homebound patient will generally require the use of supportive devices, special transportation, or the assistance of another person to travel to the appropriate facility.
>
> If a question is raised as to whether a patient is confined to the home, the HHA will be requested to furnish the intermediary with the information necessary to establish that the patient is homebound as defined above.

Regarding skilled nursing services, §40.1 states, "[t]o be covered as skilled nursing services, the services must require the skills of a registered nurse, or a licensed practical (vocational) nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury." Section 40.1.1 explains that "[s]ome services may be classified as a skilled nursing service on the basis of complexity alone, e.g., intravenous and intramuscular injections or insertion of catheters, and if reasonable and necessary to the treatment of the patient's illness or injury, would be covered on that basis." It continues, "in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse."

Section 40.1.2.1 explains that "[o]bservation and assessment of the patient's condition by a nurse are reasonable and necessary skilled services where there is a reasonable potential for change in a patient's condition that requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized."

For management and evaluation of a patient's POC, §40.1.2.2 states that "[s]killed nursing visits for management and evaluation of the patient's care plan are also reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential nonskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition." Furthermore, the CMS Medicare Beneficiary Policy

Manual, Pub. 100-02, Chapter 7, §40.1.2.1 makes clear, observation and assessment are reasonable and necessary skilled services when required to "evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized."

Section 40.1.2.3 instructs that "[t]eaching and training activities that require skilled nursing personnel to teach a patient, the patient's family, or caregivers how to manage the treatment regimen would constitute skilled nursing services. However, "[w]here it becomes apparent after a reasonable period of time that the patient, family, or caregiver will not or is not able to be trained, then further teaching and training would cease to be reasonable and necessary."

Pursuant to §40.1.2.4, "[a]lthough drugs and biologicals are specifically excluded from coverage by §1861(m)(5) of the Act, the services of a nurse that are required to administer the medications safely and effectively may be covered if they are reasonable and necessary to the treatment of the illness or injury." This section explains in relevant part:

> **A. Injections**
> Intravenous, intramuscular, or subcutaneous injections and infusions, and hypodermoclysis or intravenous feedings require the skills of a licensed nurse to be performed (or taught) safely and effectively. Where these services are reasonable and necessary to treat the illness or injury, they may be covered. For these services to be reasonable and necessary, the medication being administered must be accepted as safe and effective treatment of the patient's illness or injury, and there must be a medical reason that the medication cannot be taken orally. Moreover, the frequency and duration of the administration of the medication must be within accepted standards of medical practice, or there must be a valid explanation regarding the extenuating circumstances to justify the need for the additional injections.
>
> 1. Vitamin B-12 injections are considered specific therapy only for the following conditions:
>   - Specified anemias: pernicious anemia, megaloblastic anemias, macrocytic anemias, fish tapeworm anemia;
>   - Specified gastrointestinal disorders: gastrectomy, malabsorption syndromes such as sprue and idiopathic steatorrhea, surgical and mechanical disorders such as resection of the small intestine, strictures, anastomosis and blind loop syndrome, and
>   - Certain neuropathies: posterolateral sclerosis, other neuropathies associated with pernicious anemia, during the acute phase or acute exacerbation of a neuropathy due to malnutrition and alcoholism.
>
> For a patient with pernicious anemia caused by a B-12 deficiency, intramuscular or subcutaneous injection of vitamin B-12 at a dose of from 100 to 1000 micrograms no more frequently than once monthly is the accepted reasonable and necessary dosage schedule for maintenance treatment. More frequent injections would be appropriate in the initial or acute phase of the disease until it has been

determined through laboratory tests that the patient can be sustained on a maintenance dose.

2. Insulin Injections
   - Insulin is customarily self-injected by patients or is injected by their families. However, where a patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service.

B. Oral Medications
The administration of oral medications by a nurse is not reasonable and necessary skilled nursing care except in the specific situation in which the complexity of the patient's condition, the nature of the drugs prescribed, and the number of drugs prescribed require the skills of a licensed nurse to detect and evaluate side effects or reactions. The medical record must document the specific circumstances that cause administration of an oral medication to require skilled observation and assessment.

C. Eye Drops and Topical Ointments
The administration of eye drops and topical ointments does not require the skills of a nurse. Therefore, even if the administration of eye drops or ointments is necessary to the treatment of an illness or injury and the patient cannot self-administer the drops, and there is no one available to administer them, the visits cannot be covered as a skilled nursing service. This section does not eliminate coverage for skilled nursing visits for observation and assessment of the patient's condition. (See §40.2.1.)

For wound care, §40.1.2.8 states that skilled nursing will be covered when:

> the skills of a licensed nurse are needed to provide safely and effectively the services necessary to treat the illness or injury, is considered to be a skilled nursing service. For skilled nursing care to be reasonable and necessary to treat a wound, the size, depth, nature of drainage (color, odor, consistency, and quantity), and condition and appearance of the skin surrounding the wound must be documented in the clinical findings so that an assessment of the need for skilled nursing care can be made. Coverage or denial of skilled nursing visits for wound care may not be based solely on the stage classification of the wound, but rather must be based on all of the documented clinical findings. Moreover, the plan of care must contain the specific instructions for the treatment of the wound. Where the physician has ordered appropriate active treatment (e.g. sterile or complex dressings, administration of prescription medications, etc.) of wounds with the following characteristics, the skills of a licensed nurse are usually reasonable and necessary:

- Open wounds which are draining purulent or colored exudate or have a foul odor present or for which the patient is receiving antibiotic therapy;
- Wounds with a drain or T-tube with requires shortening or movement of such drains;
- Wounds which require irrigation or instillation of a sterile cleansing or medicated solution into several layers of tissue and skin and/or packing with sterile gauze;
- Recently debrided ulcers;
- Pressure sores (decubitus ulcers) with the following characteristics:
  - There is partial tissue loss with signs of infection such as foul odor or purulent drainage; or
  - There is full thickness tissue loss that involves exposure of fat or invasion of other tissue such as muscle or bone.

NOTE: Wounds or ulcers that show redness, edema, and induration, at times with epidermal blistering or desquamation do not ordinarily require skilled nursing care.

- Wounds with exposed internal vessels or a mass that may have a proclivity for hemorrhage when a dressing is changed (e.g., post radical neck surgery, cancer of the vulva);
- Open wounds or widespread skin complications following radiation therapy, or which result from immune deficiencies or vascular insufficiencies;
- Post-operative wounds where there are complications such as infection or allergic reaction or where there is an underlying disease that has a reasonable potential to adversely affect healing (e.g., diabetes);
- Third degree burns, and second degree burns where the size of the burn or presence of complications causes skilled nursing care to be needed;
- Skin conditions that require application of nitrogen mustard or other chemotherapeutic medication that present a significant risk to the patient;
- Other open or complex wounds that require treatment that can only be provided safely and effectively by a licensed nurse.

Section 40.1.2.13 states that "[e]ffective February 5, 1998, venipuncture for the purposes of obtaining a blood sample can no longer be the sole reason for Medicare home health eligibility. However, if a beneficiary qualifies for home health eligibility based on a skilled need other than solely venipuncture (e.g., eligibility based on the skilled nursing service of wound care and meets all other Medicare home health eligibility criteria), medically reasonable and necessary venipuncture coverage may continue during the 60-day episode under a home health plan of care."

In order to qualify for coverage of home health care, the services must be intermittent. Section 40.1.3 defines intermittent "as skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours each day for periods of 21 days or less (with

extensions in exceptional circumstances when the need for additional care is finite and predictable)."

According to §40.2.1, "[t]he service of a physical therapist, speech-language pathologist, or occupational therapist is a skilled therapy service if the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the general supervision of a skilled therapist. To be covered, the skilled services must also be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury."

Section 40.2.2 provides in relevant part:

> **A. Assessment**
> The skills of a physical therapist to assess and periodically reassess a patient's rehabilitation needs and potential or to develop and/or implement a physical therapy program are covered when they are reasonable and necessary because of the patient's condition. Skilled rehabilitation services concurrent with the management of a patient's care plan include objective tests and measurements such as, but not limited to, range of motion, strength, balance, coordination, endurance, or functional ability.
>
> *As described in section 40.2.1(b), at defined points during a course of therapy, the qualified physical therapist (instead of an assistant) must perform the ordered therapy service visit, assess the patient's function using a method which allows for objective measurement of function and comparison of successive measurements, and document the results of the assessments, corresponding measurements, and effectiveness of the therapy in the patient's clinical record. Refer to §40.2.1(b) for specific timing and documentation requirements associated with these requirements.*
>
> **B. Therapeutic Exercises**
> Therapeutic exercises, which *require the skills of a* qualified physical therapist to ensure the safety of the beneficiary and the effectiveness of the treatment constitute skilled physical therapy, *when the criteria in §40.2.1(d) above are met.*
>
> **C. Gait Training**
> Gait evaluation and training furnished *to* a patient whose ability to walk has been impaired by neurological, muscular or skeletal abnormality require the skills of a qualified physical therapist and constitute skilled physical therapy and are considered reasonable and necessary if they can be expected to materially improve the patient's ability to walk. Gait evaluation and training which is furnished to a patient whose ability to walk has been impaired by a condition other than a neurological, muscular, or skeletal abnormality would nevertheless be covered where physical therapy is reasonable and necessary to restore *function. Refer to §40.2.1(d)(1) for the reasonable and necessary coverage criteria associated with restoring patient function.*

D. Range of Motion
Only a qualified physical therapist may perform range of motion tests and, therefore, such tests are skilled physical therapy.

Range of motion exercises constitute skilled physical therapy only if they are part of an active treatment for a specific disease state, illness, or injury that has resulted in a loss or restriction of mobility (as evidenced by physical therapy notes showing the degree of motion lost and the degree to be restored). Nonskilled individuals may provide range of motion exercises unrelated to the restoration of a specific loss of function often safely and effectively. Passive exercises to maintain range of motion in paralyzed extremities that can be carried out by nonskilled persons do not constitute skilled physical therapy.

However, *if the criteria in §40.2.1(d)(3) are met*, where there is clear documentation that, because of special medical complications (e.g., susceptible to pathological bone fractures), the skills of a therapist are needed to provide services which ordinarily do not need the skills of a therapist, and then the services would be covered.

E. Maintenance Therapy
Where repetitive services that are required to maintain function involve the use of complex and sophisticated procedures, the judgment and skill of a physical therapist might be required for the safe and effective rendition of such services. If the judgment and skill of a physical therapist *are* required to safely and effectively treat the illness or injury, the services would be covered as physical therapy services. *Refer to §40.2.1(d)(3).*

F. Ultrasound, Shortwave, and Microwave Diathermy Treatments
These treatments must always be performed by or under the supervision of a qualified physical therapist and are skilled therapy.

G. Hot Packs, Infra-Red Treatments, Paraffin Baths and Whirlpool Baths
Heat treatments and baths of this type ordinarily do not require the skills of a qualified physical therapist. However, the skills, knowledge, and judgment of a qualified physical therapist might be required in the giving of such treatments or baths in a particular case, e.g., where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures, or other complications.

H. Wound Care Provided Within Scope of State Practice Acts
If wound care falls within the auspice of a physical therapist's State Practice Act, then the physical therapist may provide the specific type of wound care services defined in the State Practice Act. *However,* such visits in this specific situation *would be a covered therapy service only when the skills of a therapist are required to perform the service.*

Section 50.2 states that for home health aide services to be covered:

- The patient must meet the qualifying criteria as specified in §30;
- The services provided by the home health aide must be part-time or intermittent as discussed in §50.7;
- The services must meet the definition of home health aide services of this section; and
- The services must be reasonable and necessary to the treatment of the patient's illness or injury.

Also relevant is the CMS Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, Covered Medical and Other Health Services.

b. Overpayments and Statistical Sampling

The Medicare Carriers Manual, Part 3 – Claims Process, defines "overpayments" as "Medicare funds a physician or beneficiary has received in excess of amounts due and payable under the Medicare statute and regulations." The Medicare Manual explains that "[o]nce a determination of overpayment has been made, the amount so determined is a debt owed to the United States Government. Under the Federal Claims Collection Act of 1966, each agency or agent of the Federal Government must attempt the collection of Federal claims for money arising out of the activities of the agency." Some examples of overpayments include:

- Payment based on a charge that exceeds the reasonable charge.
- Duplicate processing of charges/claims.
- Payment to a physician on a nonassigned claim or to a beneficiary on an assigned claim.
- (Payment made to wrong payee.)
- Payment for noncovered items and services, including medically unnecessary services.
- Incorrect application of the deductible or coinsurance.
- Payment for items or services rendered during a period of nonentitlement.
- Primary payment for items or services for which another entity is the primary payer.
- Payment for items or services rendered after the beneficiary's date of death.

The CMS policy regarding statistical sampling and extrapolation can be found in the Medicare Program Integrity Manual. It requires that the Medicare contractor comply with the following conditions:

- The Medicare contractor must maintain complete documentation of the sampling methodology that was followed.
- An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in your record of how the sampling was done. A record shall be kept of the random numbers actually used in the sample and how they were selected.

> Sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged. The PSC BI units or the contractor MR units shall keep a copy of the frame.[10]

In regard to sample size, the Medicare Program Integrity Manual states the following:

> The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.
>
> In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC…shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.[11]

Chapter 3, §3.10.1.2 states that "[f]ailure…to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." Section 3.20 further explains that the overpayment amount should include the following components:

- Select the provider and period to be reviewed,
- Specify the sampling unit, universe/population, and sampling frame,

[10] Medicare Program Integrity Manual, Publication 100-08, Chapter 3, §3.10.4.4-3.10.4.1
[11] Id. at § 3.10.4.3

- Select the sample using appropriate methodology,
- Determine overpayment amount for each sampling unit, and
- Calculate point estimate and confidence interval to project or extrapolate overpayment determination

LCD L282, Physical Therapy for Home Health,[12] states the following:

Physical Therapy for Home Health (L282) – 99HH-021-L

Indications and Limitations of Coverage and/or Medical Necessity
Physical therapy services are part of a constellation of rehabilitative services designed to improve or restore physical functioning following disease, injury or loss of a body part. Physical therapists use the clinical history, systems review, physical examination, and a variety of evaluations to characterize individuals with impairments, functional limitations and disabilities. Impairments, functional limitations and disabilities thus identified are then addressed by the design and implementation of a therapeutic intervention tailored to the specific needs of the individual patient. The specific interventions most commonly utilized are exercise, heat, cold, electricity, ultraviolet light, ultrasound, hydrotherapy, and massage to improve circulation, strengthen muscles, maintain or restore motion, and train or retrain an individual to perform the activities of daily living.

General Physical Therapy Guidelines:
1. Physical therapy services are covered services provided the services are of a level of complexity and sophistication, or the patient's condition is such that the services can be safely and effectively performed only by a licensed physical therapist or under his/her supervision. Services normally considered to be a routine part of nursing care are not covered as physical therapy (i.e., turning a patient to prevent pressure injuries or walking a patient in the hallway postoperatively).
2. Covered physical therapy services must relate directly and specifically to an active written treatment regimen established by the physician, with input from the qualified physical therapist, and must be reasonable and necessary to the treatment of the individual's illness or injury.
3. Additionally, in order for the plan of care to be covered, it must address a condition for which physical therapy is an accepted method of treatment as defined by standards of medical practice, and must be for a condition that is expected to improve materially within a reasonable and generally predictable period of time or establishes a safe and effective maintenance program.
4. Therefore, physical therapy is only covered when it is rendered under a written treatment plan developed and approved by the individual's physician to address specific therapeutic goals for which modalities and procedures are planned out specifically in terms of type, frequency and duration.

[12] Determination by Palmetto GBA. Effective October 1, 2000 and retired January 23, 2011.

5. The therapist must document the patient's functional limitations in terms that are objective and measurable.
6. Rehabilitation Services for Vision Impairment
The coverage criteria and definition of rehabilitation services for vision impairment (Low Vision) is found in Transmittal AB-02-078, dated, May 28, 2002, Change Request 2083.

SPECIFIC PROCEDURE AND MODALITY GUIDELINES:
FABRICATION/APPLICATION OF SPLINTS AND STRAPPING
1. Fabrication and application as appropriate of splints and strapping (e.g., the use of elastic wraps, heavy cloth, adhesive tape) are used to enhance performance of tasks or movements, support weak or ineffective joints or muscles, reduce/correct joint limitations/deformities, and/or protect body parts from injury. The splints and strapping are often used in conjunction with therapeutic exercise, functional training, and other interventions and should be selected in the context of patient's needs and social/cultural environments.
2. The physical therapist targets the problems in performance of movements or tasks and selects (or fabricates) the most appropriate device or equipment, then fits it and trains the patient and/or caregivers in its use and application. The goal is for the patient to function at a higher level by decreasing functional limitations.
3. The simple application of a commercial splint or brace will not be considered in this section.

Application long arm splint (CPT code 29105):
Indicated for the shoulder and/or elbow in the treatment of fractures, dislocations, sprains/strains, tendinitis, post-op reconstruction, contractures or other deformities involving soft tissue.

Application forearm splint (CPT code 29125 and 29126):
Indicated for the forearm, wrist and/or hand in the treatment of fractures, dislocations, sprains/strains, tendinitis, post-op reconstruction, contractures or other deformities involving soft tissue.

Application of finger splint (CPT code 29130 and 29131):
Indicated for the finger in the treatment of fractures, dislocations, sprains/strains, tendinitis, post-op reconstruction, contractures or other deformities involving soft tissue.

Strapping of chest (CPT code 29200):
Indicated for any portion of the thorax in the treatment of fractures, dislocations, sprains/strains, tendinitis, post-op reconstruction, contractures or other deformities involving soft tissue.

Strapping of low back (CPT code 29799):

Indicated for the lumbar spine or abdominal musculature in the treatment of fractures, dislocations, sprains/strains, tendinitis, post-op reconstruction, contractures or other deformities involving soft tissue.

Strapping of shoulder (CPT code 29240):
Indicated for any portion of the shoulder girdle complex in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping of elbow or wrist (CPT code 29260):
Indicated for the elbow and wrist when there is involvement of the humerus, forearm, wrist or hand in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping of hand or finger (CPT code 29280):
Indicated when there is involvement of the hand or digits in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Application of long leg splint (CPT code 29505):
Indicated when there is involvement of the femur, patella, tibia, fibula, ankle or foot in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Application of short leg splint (CPT code 29515):
Indicated when there is involvement of the tibia, fibula, ankle or foot in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping; hip (CPT code 29520):
Indicated when there is involvement of the lower back, abdomen or hip in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping; knee (CPT code 29530):
Indicated when there is involvement of the thigh, knee or lower leg in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping; ankle (CPT code 29540):
Indicated when there is involvement of the lower leg, ankle and/or foot in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Strapping; toes (CPT code 29550):

Indicated when there is involvement of any of the toes in the treatment of contusions, dislocations, fractures, sprains/strains, post-op conditions, contractures or other deformities involving soft tissue.

Application of paste boot (CPT code 29580):
A dressing for ulcers resulting from venous insufficiency, consisting of a paste made from gelatin zinc oxide and glycerin which is applied to the leg then covered with a spiral bandage, this in turn being given a coat of the paste. The process is repeated until satisfactory rigidity is attained.

Application of foot splint (CPT code 29590):
Specific for the correction of talipes equinovarus (i.e., club foot).

Biofeedback training by any method (CPT code 90901):
The coverage criteria and definition of biofeedback is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Biofeedback peri/uro/rectal (CPT 90911)
The coverage criteria and definition of biofeedback is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Limb muscle testing, manual (CPT codes 95831)

Hand muscle testing, manual (CPT codes 95832)

Body muscle testing, manual (CPT codes 95833-and 95834)
The measurement of muscle performance using manual muscle testing only.

Range of Motion Measurements (CPT codes 95651 and 95852):

Range of Motion Measurements and Report (separate procedure); each extremity (excluding hand) or each trunk section (spine) (CPT code 95851)

Hand, With or Without Comparison With Normal Side (CPT code 95852):
Determination of range of motion using a tape measure, flexible ruler, electronic device or goniometer.

PT Evaluation (CPT code 97001) and PT Re-evaluation (CPT code 97002):
Evaluations are required prior to beginning therapy for determining the medical necessity of initiating rehabilitative or maintenance services. Patients must exhibit a change from normal physical functional ability to warrant an evaluation. Such evaluations must state the reason for the initial referral. Components of

evaluations include the patient history, relevant review of systems, pertinent physical assessment and tests/measurements.

Factors that influence the complexity of the examination and evaluation process include the clinical findings, extent of loss of function, social considerations, and the patient's overall physical function and health status. Thus, the evaluation reflects the chronicity or severity of the current problem, the possibility of multi-site or multi-system involvement, the presence of preexisting systemic conditions or diseases, and the stability of the condition. Physical therapists also consider the level of the current impairments and the probability of prolonged impairment, functional limitation, and disability; the living environment; and the social supports (i.e., the potential for effecting an improvement in the patient's functional ability).

Re-evaluations are appropriate periodically to assess progress toward goals established in the plan of care, or to identify and establish interventions for newly developed physical impairments. The components or re-evaluations are the same as the initial evaluation, but are focused on assessing changes from the initial evaluation or progress toward treatment goals.

Initial evaluations or re-evaluations may be considered reasonable and necessary even when the evaluation determines that skilled rehabilitation services are not required if the patient's condition showed a need for an evaluation, or even if the goals established by the plan of care are not realized. Routine screening and assessments during admission to home health care, and routine reassessments are not covered.

Designing and Implementing a Maintenance Program:

1. Periodic evaluations of the patient's condition and response to treatment may be covered when reasonable and necessary if the judgment and skills of a qualified physical therapist are required:
    a. The design of a maintenance regimen required to delay or minimize muscular and functional deterioration in patients suffering from a chronic disease may be considered reasonable and necessary
    b. Limited services may be considered reasonable and necessary to establish and assist the patient and/or their caregiver with the implementation of a safe and effective rehabilitation maintenance program
    c. Re-evaluations required to assess the patient's condition and adjust the program may be considered reasonable and necessary
2. It is not reasonable and necessary for a physical therapist to perform or supervise maintenance programs that do not require the skills of a physical therapist. These situations include:
    a. Services related to activities for the general good and welfare of patients (i.e., General exercises to promote overall fitness and flexibility)

b. Repetitive exercises to maintain gait or maintain strength and endurance, and assisted walking, such as that provided in support for feeble and unstable patients;
c. Range of motion and passive exercises that are not related to restoration of a specific loss of function, but are useful in maintaining range of motion in paralyzed extremities
d. Maintenance therapies after the patient has achieved therapeutic goals or for patients who show no further material improvement

Hot or Cold Packs therapy (CPT code 97010):

1. Hot or cold packs are used primarily in conjunction with therapeutic procedures to provide analgesia, relieve muscle spasm and reduce inflammation and edema. Typically, cold packs are used for acute, painful conditions, and hot packs for subacute or chronic painful conditions.
2. Heat treatments and baths of this type ordinarily do not require the skills of a qualified physical therapist. However, the skills, knowledge and judgment of a qualified physical therapist might be required in the giving of such treatments or baths in a particular case, e.g., where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures or other complications.
3. Hot or cold packs applied in the absence of associated procedures or modalities, or used alone to reduce discomfort are considered not reasonable and necessary and therefore, are not covered.

Mechanical Traction therapy (CPT code 97012):

1. Traction is generally limited to the cervical or lumbar spine with the hope of relieving pain in or originating from those areas.
2. Specific indications for the use of Mechanical Traction include:
   a. Cervical and/or lumbar radiculopathy
   b. Back disorders such as disc herniation, lumbago, and sciatica

Vasopneumatic Device Therapy (CPT code 97016):

1. The use of Vasopneumatic Devices may be considered reasonable and necessary for the application of pressure to an extremity for the purpose of reducing edema.
2. Specific indications for the use of Vasopneumatic Devices include:
   a. Reduction of edema after acute injury
   b. Lymphedema of an extremity
   c. Education on the use of a lymphedema pump for home use

Note: Further treatment of lymphedema by a physical therapist after the educational visits are generally not reasonable and necessary. Generally, education can be completed in three visits.

Paraffin Bath (CPT code 97018) Whirlpool (CPT code 97022):
Heat treatments and baths of this type ordinarily do not require the skills of a qualified physical therapist. However, the skills, knowledge and judgment of a qualified physical therapist might be required in the giving of such treatment or baths in a particular case, e.g., where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures or other complications.

Diathermy Treatment (CPT code 97024):
The coverage criteria and definition of Diathermy Treatment is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Infrared Therapy (CPT code 97026):
The coverage criteria and definition of Infrared Therapy is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Application of a modality to one or more areas, electrical stimulation, manual, each 15 minutes (CPT code 97032)
1. This modality includes the following types of electrical stimulation:
The coverage criteria and definition of electrical stimulation is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Electromagnetic Therapy (HCPCS code G0329)
The coverage criteria and definition of electromagnetic therapy is found in the CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (Internet-Only Manual.)

Contrast Bath Therapy (CPT code 97034)
1. Contrast Baths are a special form of therapeutic heat and cold that can be applied to distal extremities. The effectiveness of contrast baths is thought to be due to reflex hyperemia produced by the alternating exposure to heat and cold. Although a variety of applications are possible, Contrast Baths often are used in treatment programs for rheumatoid arthritis and reflex sympathetic dystrophy.
2. The use of Contrast Baths is considered reasonable and necessary to desensitize patients to pain by reflex hyperemia produced by the alternating exposure to heat and cold.
3. Specific indications for the use of Contrast Baths include:
   a. The patient having pain associated with rheumatoid arthritis or other inflammatory arthritis
   b. The patient having reflex sympathetic dystrophy
   c. The patient having a sprain or strain resulting from an acute injury

4. Heat treatments and baths of this type ordinarily do not require the skills of a qualified physical therapist. However, the skills, knowledge and judgment of a qualified physical therapist might be required in the giving of such treatments or baths in a particular case, e.g., where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fracture or other complications.

Ultrasound Therapy (CPT code 97035)

1. Therapeutic Ultrasound is a deep heating modality that produces a sound wave of 0.8 to 3.0 MHz. In the human body ultrasound has several pronounced effects on biologic tissues. It is attenuated by certain tissues and reflected by bone. Thus, tissues lying immediately next to bone can receive an even greater dosage of ultrasound, as much as 30% more. Because of the increased extensibility ultrasound produces in tissues of high collagen content, combined with the close proximity of joint capsules, tendons, and ligaments to cortical bone where they receive a more intense irradiation, it is an ideal modality for increasing mobility in those tissues with restricted range of motion.
2. The application of ultrasound is considered reasonable and necessary for patients requiring deep heat to a specific area for reduction of pain, spasm, and joint stiffness, and the increase of muscle, tendon and ligament flexibility.
3. Specific indications for the use of Ultrasound Application include:
   a. The patient having tightened structures limiting joint motion that require an increase in extensibility
   b. The patient having symptomatic soft tissue calcification
   c. The patient having neuromas

Note: Ultrasound Application is not considered to be reasonable and necessary for the treatment of asthma, bronchitis or any other pulmonary condition.

GENERAL GUIDELINES FOR THERAPEUTIC PROCEDURES:

1. Therapeutic procedures are procedures that attempt to reduce impairments and improve function through the application of clinical skills and/or services.
2. Use of these procedures requires that the therapist have direct (one to one) patient contact.
3. Therapeutic exercises and neuromuscular reeducation are examples of therapeutic interventions. The expected goals documented in the treatment plan, effected by the use of each of these procedures, will help define whether these procedures are reasonable and necessary. Therefore, since any one or a combination of more than one of these modalities may be used in a treatment plan, documentation must support the use of each modality as it relates to a specific therapeutic goal.
4. Services provided concurrently by a physical therapist and occupational therapist may be covered if separate and distinct goals are documented in the treatment plans.

Therapeutic Exercises (CPT code 97110):

1. Therapeutic Exercise is performed with a patient either actively, active-assisted, or passively participating (e.g., treadmill, isokinetic exercise, lumbar stabilization, stretching and strengthening).
2. Therapeutic Exercise is considered reasonable and necessary if at least one of the following conditions is present and documented:
   a. The patient having weakness, contracture, stiffness secondary to spasm, spasticity, decreased range of motion, gait problem, balance and/or coordination deficits, abnormal posture, muscle imbalance.
   b. The patient needing to improve mobility, stretching, strengthening, coordination, control of extremities, dexterity, range of motion, or endurance as part of activities of daily living training, or re-education.
3. Documentation for Therapeutic Exercise must show objective loss of joint motion, strength or mobility (e.g., degrees of motion, strength grades, or levels of assistance).

Neuromuscular Reeducation (CPT code 97112):

1. This therapeutic procedure is provided to improve balance, coordination, kinesthetic sense, posture, and proprioception (e.g., proprioceptive neuromuscular facilitation, Feldenkreis, Bobath, BAP's boards, and desensitization techniques).
2. Neuromuscular Re-education may be considered reasonable and necessary if at least one of the following conditions is present and documented:
   a. The patient having the loss of deep tendon reflexes and vibration sense accompanied by paresthesia, burning, or diffuse pain of the feet, lower legs, and/or fingers
   b. The patient having nerve palsy, such as peroneal nerve injury causing foot drop
   c. The patient having muscular weakness or flaccidity as a result of a cerebral dysfunction, a nerve injury or disease, or having had a spinal cord disease or trauma

Gait Training Therapy (CPT code 97116):

1. This procedure may be reasonable and necessary for training patients whose walking abilities have been impaired by neurological, muscular, or skeletal abnormalities or trauma.
2. Specific indications for gait training include:
   a. The patient having suffered a cerebral vascular accident resulting in impairment in the ability to ambulate, now stabilized and ready to begin rehabilitation
   b. The patient having recently suffered a musculoskeletal trauma, requiring ambulation re-education
   c. The patient having a chronic, progressively debilitating condition for which safe ambulation has recently become a concern
   d. The patient having had an injury or condition that requires instruction in the use of a walker, crutches, or cane

e. The patient having been fitted with a brace/lower limb prosthesis and requires instruction in ambulation
f. The patient having a condition that requires retraining in stairs/steps or chair transfer in addition to general ambulation

3. Gait training is not considered reasonable and necessary when the patient's walking ability is not expected to improve.
4. Repetitive walk-strengthening exercise for feeble or unstable patients or to increase endurance does not require professional skills and will be denied as not reasonable and necessary.

Massage Therapy (CPT code 97124):

1. Massage is the application of systemic manipulation to the soft tissues of the body for therapeutic purposes. Although various assistive devices and electrical equipment are available for the purpose of delivering massage, use of the hands is considered the most effective method of application, because palpation can be used as an assessment as well as a treatment tool.
2. Massage Therapy, including effleurage, ptrissage, and/or tapotement (stroking, compression, percussion) may be considered reasonable and necessary if at least one of the following conditions is present and documented:
   a. The patient having paralyzed musculature contributing to impaired circulation
   b. The patient having sensitivity of tissues to pressure
   c. The patient having tight muscles resulting in shortening and/or spasticity of affected muscles
   d. The patient having abnormal adherence of tissue to surrounding tissue
   e. The patient requiring relaxation in preparation for neuromuscular re-education or therapeutic exercise
   f. The patient having contractures and decreased range of motion

3. In most cases, postural drainage and pulmonary exercises can be carried out safely and effectively by nursing personnel. If the attending physician determines that for the safe and effective administration of these procedures, the skills of a physical therapist are required, coverage may be allowed.

Manual Therapy (CPT code 97140):

The goal of this type of therapy is to reduce lymphedema of an extremity by routing the fluid to functional pathways, preventing backflow as the new routes become established, and to use the most appropriate methods to maintain the reduction of the extremity after therapy is complete. This therapy involves intensive treatment to reduce the size of the extremity by a combination of manual decongestive therapy and serial compression bandaging, followed by an exercise program.

1. It is expected that during these sessions, education is being provided to the patient and or caregiver on the correct application of the compression bandage.

2. It is also expected that after the completion of the therapy the patient and or caregiver can perform these activities without supervision.

Joint Mobilization (Peripheral or Spinal):
This procedure may be considered reasonable and necessary if restricted joint motion is present and documented. It may be reasonable and necessary as an adjunct to therapeutic exercises when loss of articular motion and flexibility impedes the therapeutic procedure.

Orthotics Training (CPT code 97760):
1. This procedure may be considered reasonable and necessary if there is an indication for education on the application of the orthotic, the orthotic is in the home and the functional use of the orthotic is documented. Generally, orthotic training can be completed in three visits.
2. The medical record should document the distinct treatments rendered when orthotic training for a lower extremity is done during the same visit as gait training (CPT code 97116) or self-care/home management training (CPT code 97535).
3. The patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases the patient may not be able to perform this function, but a responsible individual can be trained to use the device.

Prosthetic Training (CPT code 97761):
1. This procedure may be considered reasonable and necessary if there is an indication for education on the application of the prosthesis, the prosthesis is in the home and the functional use of the prosthetic is documented.
2. The medical record should document the distinct goals and service rendered when prosthetic training for a lower extremity is done during the same visit as gait training (CPT code 97116) or self care/home management training (CPT code 97535)
3. Periodic revisits beyond the third month would require documentation to support medical necessity.

Therapeutic Activities (CPT code 97530):
1. Therapeutic activities are considered reasonable and necessary for patients needing a broad range of rehabilitative techniques that involve movement. Movement activities can be for a specific body part or could involve the entire body. This procedure involves the use of functional activities (e.g., bending, lifting, carrying, reaching, catching, and overhead activities) to improve functional performance in a progressive manner. The activities are usually directed at a loss or restriction of mobility, strength, balance, or coordination. They require the skills of a physical therapist and are designed to address a specific functional need of the patient. These dynamic activities must be part of an active treatment plan and be directed at a specific outcome.

2. In order for Therapeutic Activities to be covered, the following requirements must be met:
   a. The patient having a condition for which therapeutic activities can reasonably be expected to restore or improve functioning
   b. The patient's condition being such that he/she is unable to perform therapeutic activities except under the direct supervision of a physician or physical therapist
   c. There being a clear correlation between the type of exercise performed and the patient's underlying medical condition for which the therapeutic activities were prescribed

Self-Care Management Training (CPT code 97535):

1. This procedure is reasonable and necessary only when it requires the skills of a physical therapist, when it is designed to address specific needs of the patient, and when it is part of an active treatment plan directed at a specific outcome.
2. The patient must have a condition for which training in activities of daily living is reasonable and necessary, and such training must be reasonably expected to restore or improve the functioning of the patient. Documentation must relate the training to expected functional goals that are attainable by the patient.
3. The patient and/or caregiver must have the capacity to learn from instructions.
4. Services provided concurrently by physical therapists and occupational therapists may be covered if separate and distinct goals are documented in the treatment plans.

Community/Work Reintegration (CPT code 97537,97545, and 97546):

Physical therapy services that are related ***solely*** to specific employment opportunities, work skills, or work settings are not reasonable and necessary for the diagnosis and treatment of an illness or injury and are excluded from coverage by section 1862(a)(1)(A) of the Social Security Act.

Wheelchair Management Training (CPT code 97542):

1. This service trains the patient in functional activities that promote optimal safety, mobility and transfers. Patients who are wheelchair bound may occasionally need skilled input on positioning to avoid pressure points, contractures, and other medical complications.
2. This procedure is reasonable and necessary only when it requires the skills of a physical therapist is designed to address specific needs of the patient, and must be part of an active treatment plan directed at a specific goal.
3. The patient and/or caregiver must have the capacity to learn from instructions.
4. Typically three to four sessions should be sufficient to teach the patient and/or caregiver these skills.
5. When billing 97542 for wheelchair propulsion training, documentation must relate the training to expected functional goals that are attainable by the patient and/or caregiver.

Prosthetic Checkout (CPT Code 97762):

1. These assessments are reasonable and necessary when there is a modification of the orthotic/prosthetic device.
2. These assessments may be reasonable and necessary when patients experience a loss of function directly related to the device (e.g., pain, skin breakdown, and falls).
   a. These assessments are not reasonable and necessary when a device is newly issued or is reissued or replaced after normal wear.

Physical Performance Test or Measurement (CPT code 97750):
This testing may be reasonable and necessary for patients with neurological or musculoskeletal conditions when such tests are needed to formulate or evaluate a specific treatment plan, or to determine a patient's functional capacity.

CMS National Coverage Policy:

Title XVIII of the Social Security Act, §1862 (a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(7) excludes routine physical examinations.

CMS Manual System, Pub 100-02, Medicare Benefit Policy, Chapter 7, §§ 30.4, 40, and 40.2.1

CMS Manual System, Pub 100-03, Medicare National Coverage Determinations, Chapter 1, Part 1, §§30.1 and 30.1.1

CMS Manual System, Pub 100-03, Medicare National Coverage Determination, Chapter 1, Part 2. §§150.5, 160.7, 160.7.1, 160.12, 160.13, and 160.15.

CMS Manual System, Pub 100-03, Medicare National Coverage Determination, Chapter 1, Part 3, §170.1.

CMS Manual System, Pub. 100-03, Medicare National Coverage Determination, Chapter 1, Part 4 §§270.1, 270.6 and 280.13

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, §11.2

CMS Manual System, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §§13.1.1-13.13.14

Transmittal AB-02-078, Dated May 28, 2002, Change Request 2083.

CMS Manual System, Pub 100-02, Medicare Benefit Policy, Transmittal 111, dated September 25, 2009, Change Request 6005

Related Documents
Articles
A21618
A22020

DOCUMENTATION REQUIREMENTS

1. HCFA forms 700/701 are not required.
2. The plan of treatment written by and approved by the certifying physician must be included in the patient's medical record.
3. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the Intermediary upon request.
4. Associated with several procedure codes are guidelines on the number of visits generally needed to accomplish the task. If more visits are needed the documentation should support the necessity of the additional visits.
5. *CORF social and/or psychological services do not include services for mental health diagnoses. Social and/or psychological services are covered only if the patient's physician or the CORF physician establishes that the services directly relate to the patient's rehabilitation plan of treatment and are needed to achieve the goals in the rehabilitation plan of treatment. Social and/or psychological services are those services that address the patient's response and adjustment to the rehabilitation treatment plan: rate of improvement and progress towards the rehabilitation goals, or other services as they directly relate to the physical therapy plan of treatment being provided to the patient.*

Evaluation/Re-evaluations:
The physician and/or the physical therapist evaluation/re-evaluation assesses the area for which physical therapy treatment is being planned. It must be completed prior to beginning therapy. Evaluations must contain the following information:

1.Reason for referral
2. Diagnosis/condition being treated
3.Past level of function (be specific)
4.4. Evaluations must contain physical and cognitive baseline data necessary for assessing rehabilitation potential and measuring progress
5.Current level of function
6.Measurements such as strength, ROM, pain level
7.Treatment modalities selected for treating current illness or injury
8.Limitations which may influence the length of treatment
9.Short and long term goals stated in measurable terms, and the expected date of accomplishment
10. Frequency and duration of therapy

Treatment Plan:
Services are to be furnished according to a written Plan of Treatment determined by the certifying physician, with input from the qualified physical therapist, after

an appropriate assessment (evaluation) of the condition (illness or injury) is completed and before active therapy begins. The Plan of Treatment may not be altered by a physical therapist without a supplemental order from the certifying physician. The Plan of Treatment must contain the following elements:

1. Diagnosis being treated and the structural impairment/functional limitation that are to be addressed
2. Specific treatment modalities or procedures being used for each specific problem to attain the stated goals
3. Specific functional goals for therapy in measurable terms
4. Amount, frequency, and duration of each therapeutic modality
5. Rehabilitation potential - therapists/physician's expectation of the patient's ability to meet the goals at initiation of treatment

Clinical/Progress Notes:
A clinical note should be written for each visit. It should contain the objective status of the patient, a description of the services performed, the patient's response to the services and the progress toward the treatment goals.

1. The clinical note should document any treatment variations with the associated rationale.
2. The clinical or progress notes should be written using measurements and functional accomplishments. Use statements which can be used to assess the patient's response to therapy such as:
   a. Able to perform exercises as prescribed for 15 reps"
   b. "Able to safely transfer from bed to wheelchair with standby assistance"
   c. Can now abduct shoulder 120 degrees"
   d. Can bridge now sufficiently to pull slacks up over hips"
3. Avoid terms such as:
   a. Doing well
   b. Improving
   c. Less pain
   d. Increased range of motion
   e. Increased strength
   f. Tolerated treatment well

Certification/Re-certification:
Certifications are required upon initiation of therapy and at least every sixty days thereafter for Home Health.

1. The referring/attending physician must sign all certifications/recertifications. Signature means an actual handwritten signature or electronic signatures.
2. Documentation should indicate the prognosis for potential restoration of function in a reasonable and generally predictable period of time, or the need to establish a safe and effective maintenance program.

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation

of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters. They are binding on all HCFA components, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Appeals Council, and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

HCFA Ruling 95-1 states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provisions, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied. HCFA Ruling 95-1 states:

> Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the following reasons. The services or items were:
>
> - not reasonable and necessary under section 1862(a)(1) of the Act; HCFAR 95-1-3
> - for custodial care and, therefore, not covered under section 1862(a)(9) of the Act; denied because the beneficiary was unintentionally, inadvertently, or erroneously placed into a noncertified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act), as referenced by section 1879(e) of the Act; or
> - noncovered home health services furnished to a beneficiary who was not "homebound" or who did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act), as referenced by section 1879(g) of the Act.
>
> The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases listed above) were excluded from coverage. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a postpayment audit review.

ANALYSIS

A. Home Health Services

Medicare home health covers limited, specifically defined, at-home care related to identified medical conditions and includes personal care services. Medicare home health services must be prescribed by a physician, and provided through a licensed home health agency. See, §§1861(m) and 1861(o) of the Act and 42 CFR §409.42. The beneficiary must have a medical condition, or combination of conditions, that require periodic services from a skilled nurse or therapist (Id.).

A plan of care must be developed that describes the specific services covered (Id.; 42 CFR §409.42).

To qualify for Medicare home health services, the beneficiary must be homebound. See, Medicare Benefit Policy Manual, Pub. 100-02, Chapter 17, §30.1 and 42 CFR §409.42. This means it would require a considerable and taxing effort for the beneficiary to leave the home (Id.). Section 30.1 of the Medicare Benefit Policy Manual explains that an individual does not have to be bedridden to be considered confined to the home. However, the condition of the beneficiary should be such that there exists a normal inability to leave home.

The beneficiary must be in need of skilled services on an intermittent basis. See, 42 CFR §409.42. For purposes of benefit eligibility, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, "intermittent" means skilled nursing care that is either provided or needed on fewer than seven (7) days each week or less than eight (8) hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

Furthermore, skilled services are those which are of such complexity that they can be safely and effectively performed only by, or under the direct supervision, of professional personnel. See, the Medicare Benefit Policy Manual, Chapter 7, §§40.1 and 40.2. Section 40.1.1 explains that "[s]ome services may be classified as a skilled nursing service on the basis of complexity alone, e.g., intravenous and intramuscular injections or insertion of catheters, and if reasonable and necessary to the treatment of the patient's illness or injury, would be covered on that basis." It continues that "in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse." See also, 42 CFR §409.42(b).

While drugs and biologicals are specifically excluded from coverage by §1861(m)(5) of the Act, §40.1.2.3 explains that the services of a nurse that are required to administer medications safely and effectively may be covered if they are reasonable and necessary to the treatment of the illness or injury. Injections are covered if they require the skills of a licensed nurse to be performed (or taught) safely and effectively. The manual states that insulin is customarily self-injected by the beneficiary or their family. However, if the beneficiary is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing, the injections are considered a reasonable and necessary skilled nursing service. Similarly, §40.1.2.13 states that "[e]ffective February 5, 1998, venipuncture for the purposes of obtaining a blood sample can no longer be the sole reason for Medicare home health eligibility. However, if a beneficiary qualifies for home health eligibility based on a skilled need other than solely venipuncture (e.g., eligibility based on the skilled nursing service of wound care and meets all other Medicare home health eligibility criteria), medically reasonable and necessary venipuncture coverage may continue during the 60-day episode under a home health plan of care."

Section 40.1.2.1 explains that "[o]bservation and assessment of the patient's condition by a nurse are reasonable and necessary skilled services where *there is a reasonable potential for* change in

a patient's condition *that* requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized."

Please see attached addendum for Beneficiary-specific analysis discussions.

B. Overpayment

Section 1879 of the Social Security Act permits Medicare payments to be made to providers on assigned claims for certain services otherwise not covered, if neither the beneficiary nor the provider knew, or could reasonably be expected to know, that the services were not covered. Services affected are those disallowed as not medically reasonable or necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.

Beneficiaries may not be billed for any overpayment amount that is refunded by offsetting against future Medicare payments payable to you by reason of assignment. Under provisions of Section 1879 of the Social Security Act, beneficiaries are exempt from any liability for services which they did not know (or could not have reasonably been expected to know) would not be allowed and paid for by Medicare.

HCFA Ruling 95-1 explains that Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the following reasons. The services or items were:

- not reasonable and necessary under section 1862(a)(1) of the Act; HCFAR 95-1-3
- for custodial care and, therefore, not covered under section 1862(a)(9) of the Act; denied because the beneficiary was unintentionally, inadvertently, or erroneously placed into a noncertified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act), as referenced by section 1879(e) of the Act; or
- noncovered home health services furnished to a beneficiary who was not "homebound" or who did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act), as referenced by section 1879(g) of the Act.

The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases listed above) were excluded from coverage. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a postpayment audit review. The undersigned ALJ finds that Beneficiary liability is waived as there is no evidence that the Beneficiaries knew or reasonably could have been expected to know that the items/services were excluded from coverage.

Provider liability is not waived. Section 1870 of the Act prohibits adjustment or recovery of an overpayment where the provider is deemed to be without fault. According to the CMS Medicare Financial Management Manual, Publication 100-6, Chapter 3, §90:

> A provider is liable for overpayments it received unless it is found to be without fault. The FI or carrier, as applicable, makes this determination.
>
> The FI or carrier considers a provider without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e.,
>
> - It made full disclosure of all material facts; and
> - On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier's attention.
>
> Normally, it will be clear from the circumstances whether the provider was without fault in causing the overpayment. Where it is not clear, the FI or carrier shall develop the issue.

In the instant matter, it is clear the provider is not without fault. The Appellant is responsible for knowing proper Medicare billing procedures. The Appellant should have known the appropriate guidelines and regulations required for coverage of home health services. Accordingly, the provider's liability and overpayment recovery cannot be waived under §§ 1870 and 1879.

C. Statistical Sampling

Health Integrity determined the overpayment amount by using a computer-generated random sample of claims submitted by the Appellant for the procedure codes G0151, G0154, G0155, G0156, with dates of service from July 1, 2006 through January 31, 2009 (Master File, Ex. 6, p. 1). The sample only included claims for Beneficiaries that received at least one (1) service representing procedure code(s) that was paid by Medicare (Master File, Ex. 6, p. 2). Other services that were billed in conjunction with these codes that were the focus of the review were also audited (Id.). Health Integrity reviewed these claims in conjunction with the medical records to ensure that the services billed were properly supported by the required medical record documentation (Id.).

Health Integrity explained that it obtained "a statistically valid random sample of processed Medicare claims in accordance with the procedure outlined in the Medicare Program Integrity Manual (PIM). For a statistically valid random sample, the medical review staff and Zone Program Integrity Contractor statisticians select a sample whereby each element in the sample has an equal opportunity of being selected and is thus representative of the original universe" (Master File, Ex. 6, p. 2). Health Integrity continued by stating that it used "a statistically valid random sample of claims from the overall universe, [that were] considered to be representative of [the Appellant's] billing practices. Therefore, the actual calculated overpayment from the claim sample of 54 claims has been extrapolated from the entire number of 10,699 claims. This has yielded a total overpayment of $12,589,185.0" (Id.).

Health Integrity's sampling unit was each claim (Master File, Ex. 6, p. 4). Health Integrity used a two (2) strata sample with twenty-seven claims in each stratum for a total of fifty-four claims in the sample (Id.). Stratum one (1) was for claims with payments between $1000 and $3000 and Stratum two (2) was for claims with payments between $3000 and $6000 (Id.). The fifty-four claims were randomly selected from the 10,699 claims in the universe (Id.). The selection was done, using a statistical analysis system (SAS), in such a manner that each and every claim in the universe had an equal chance of being selected (Id.).

According to Health Integrity, the "Overpayment for Sample" is the exact amount of incorrect payment for the services in the sample (Id.). This amount is determined based on the review of the medical records (Id.). The actual overpayment for the sample is the sum of the actual overpayments for the two (2) strata (Id.). The actual overpayment for stratum one (1) was $36,301.94 (Id.). The actual overpayment for stratum two (2) was $45,379.09 (Id.). The actual overpayment for the sample was $81,681.03 (Id.).

Health Integrity explained that the "Average Overpayment per Unit for Each Stratum" is calculated by dividing the "Overpayment for the respective stratum" by the number of units in the stratum (Id.). The average overpayment for stratum one (1) was $1,344.52 ($36,301.94/27) (Id.). The average overpayment for stratum two (2) was $1,680.71 ($45,379.09/27) (Id.). Health Integrity further explained that the "Projected Overpayment for Population" is the amount that Home Health believes the Appellant has been overpaid for all services in the universe (Id.). This amount was calculated by summing the product of the average overpayment amount per unit by the total number of units in the respective stratum (($1,344.52 x 8,649) + ($1,680.71 x 2,050) = $15,074,171) (Id.).

Health Integrity noted that the overpayment was then calculated based on the outcome of reviewing the medical records for services in a statistically valid randomly selected sample, rather than reviewing all the services in the universe (Master File, Ex. 6, p. 5). Health Integrity argued that it is 90% confident that the overpayment was at least $12,589,185, and therefore that was the requested amount (Id.).

This sampling methodology is outlined in the CMS Medicare Program Integrity Manual, Publication 100-8, §§3.10.1.3-3.10.1.4. The manual states in relevant part:

> The major steps in conducting statistical sampling are: (1) selecting the provider or supplier; (2) selecting the period to be reviewed; (3) defining the universe, the sampling unit, and the sampling frame; (4) designing the sampling plan and selecting the sample; (5) reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collection of the overpayment.
>
> The PSC and Medicare contractor BI and MR units shall use statistical sampling when it has been determined that a sustained or high level of payment error exists, or where documented educational intervention has failed to correct the

payment error. A sustained or high level of payment error may be determined to exist through a variety of means, including, but not limited to:

- error rate determinations by MR unit, PSC, BI unit, or other area
- probe samples
- data analysis
- provider/supplier history
- information from law enforcement investigations
- allegations of wrongdoing by current or former employees of a provider or supplier
- audits or evaluations conducted by the OIG

Once a determination has been made that statistical sampling may be used, factors also to be considered for determining when to undertake statistical sampling for overpayment estimation instead of a claim-by-claim review include, but are not limited to: the number of claims in the universe and the dollar values associated with those claims; available resources; and the cost effectiveness of the expected sampling results.

Medicare policy dictates that "[s]o long as proper procedures for the execution of probability sampling have been followed ... [a] challenge to the validity of the sample...is without merit as it fails to taken into account all the other factors that are involved in the sample design." See, CMS Medicare Program Integrity Manual, Publication 100-08, Chapter 3, §3.10.4.3. In this case, Health Integrity has demonstrated that "proper procedures" were followed. Ms. Pu testified that Health Integrity complied with the steps as outlined in the CMS Medicare Program Integrity Manual. She testified that the statistical sample was undertaken because the typical home health benefit lasts for two (2) consecutive episodes. However, the Appellant's average was five (5) plus consecutive episodes. Health Integrity concluded that this difference warranted investigation. The benchmark was five plus (5+) sixty day episodes in about a three (3) year timeframe between 1996 and 1999. The Appellant was the highest in the state of Texas for having a pattern of continuous episodes. Over sixty percent of the Appellant's patients received five (5) plus continuous episodes.

Ms. Pu testified that the universe was defined as all claims from beneficiaries with five plus (5+) home health care episodes with payments between $1,000 and $6,000 billed for services rendered between July 1, 2006 and July 31, 2009.

Ms. Pu next testified that the sampling unit was a claim. A two (2) strata sample was used with 27 claims in each stratum for a total of 54 claims in the sample. Stratum one (1) was for claims with payments between $1,000 and $3,000. Stratum two (2) was for claims with payments between $3,000 and $6,000. The 54 claims were randomly selected in such a manner that each and every claim in the universe had an equal chance of being selected in compliance with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.11.1 states that generally "a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying." Ms. Pu pointed out that this section also states "that even if the allocation is not optimal, using

stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample."

Ms. Pu further testified that in accordance with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.4.2 Health Integrity used the software statistical package RAT-STATS. Pursuant to with the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.5.1, Health Integrity used the lower limit of the one-sided 90 percent confidence interval. Ms. Pu explained that this is a conservative method and works to the financial advantage of the provider.

Regarding the Appellant's argument that Health Integrity had no probe sample for error rate or variability, Ms. Pu testified that the CMS Medicare Program Integrity Manual, Pub. 100-08, Chapter 8, §8.4.1.4 that payment error may be determined through many ways, including, but not limited to: error rate determinations by MR unit, PSC, ZPIC, or other area; probe samples; data analysis; provider/supplier history; information from law enforcement investigations; allegations of wrongdoing by current or former employees of a provider or supplier; audits or evaluations conducted by OIG. Accordingly, Ms. Pu argued that using a data analysis instead of a probe sample complies with Medicare guidelines.

Ms. Pu next addressed the Appellant's argument that the sample was not representative of the universe. She testified that pursuant to both the visual check of distribution and the statistical hypothesis testing for differences, the results both demonstrated that the sample is representative of the universe.

Regarding precision, Ms. Pu testified that Health Integrity followed all Medicare guidelines and that the precision in this case is not unusual. She explained that there is always uncertainty in sample design. Additionally, the lower bound of a 90% confidence interval incorporates the precision. It accounts for lack of precision to the Appellant's advantage.

Ms. Pu testified that Health Integrity follows the CMS Medicare Program Integrity Manual regarding underpayments. She explained that if an underpayment is found, it is factored into the extrapolation.

Both Dr. Cobb and Dr. Witmer agreed with many of Ms. Pu's points. While Dr. Cobb and Dr. Witmer provided testimony establishing that a larger sample size would have been better, the undersigned ALJ finds that neither Dr. Cobb nor Dr. Witmer established that Health Integrity failed to comply with applicable Medicare rules and guidelines. Therefore, undersigned ALJ finds that Health Integrity has fulfilled the requirements as stated in the Medicare Program Integrity Manual with respect to the sampling methodology and the statistical sample.

VII. CONCLUSION

The Medicare statutory requirements and guidelines have been met for the home health services provided to multiple Medicare Beneficiaries,[13] for dates of service ranging from July 1, 2006 through January 31, 2009, as indicated on the attached addendum. Regarding claims that have been denied, the limitation of liability provisions of §1879 of the Act do not apply. Further, §1870(b)(1)(B) of the Act does not apply as the Appellant as the Appellant was not without fault. Finally, the undersigned ALJ finds that the statistical sampling methodology used is valid.

VIII. ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

JUN 0 8 2012
Date

Lauren Heard
Administrative Law Judge

13

All Amendments to the United States Constitution

Amendments 1-10 | Amendments 11-27

Congress of the United States
begun and held at the City of New-York, on
Wednesday the fourth of March, one thousand seven hundred and eighty nine.

THE Conventions of a number of the States, having at the time of their adopting the Constitution, expressed a desire, in order to prevent misconstruction or abuse of its powers, that further declaratory and restrictive clauses should be added: And as extending the ground of public confidence in the Government, will best ensure the beneficent ends of its institution.

RESOLVED by the Senate and House of Representatives of the United States of America, in Congress assembled, two thirds of both Houses concurring, that the following Articles be proposed to the Legislatures of the several States, as amendments to the Constitution of the United States, all, or any of which Articles, when ratified by three fourths of the said Legislatures, to be valid to all intents and purposes, as part of the said Constitution; viz.

ARTICLES in addition to, and Amendment of the Constitution of the United States of America, proposed by Congress, and ratified by the Legislatures of the several States, pursuant to the fifth Article of the original Constitution.

> *Note: The following text is a transcription of the first ten amendments to the Constitution in their original form. These amendments were ratified December 15, 1791, and form what is known as the "Bill of Rights."*

AMENDMENT I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

AMENDMENT II

A well regulated Militia, being necessary to the security of a free State, the right of the people to keep and bear Arms, shall not be infringed.

AMENDMENT III

No Soldier shall, in time of peace be quartered in any house, without the consent of the Owner, nor in time of war, but in a manner to be prescribed by law.

AMENDMENT IV

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

AMENDMENT V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

AMENDMENT VI

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defence.

AMENDMENT VII

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

AMENDMENT VIII

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

AMENDMENT IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

AMENDMENT X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

AMENDMENT XI - Passed by Congress March 4, 1794. Ratified February 7, 1795.

Note: Article III, section 2, of the Constitution was modified by amendment 11.

28 USC 1254: Courts of appeals; certiorari; certified questions
Text contains those laws in effect on June 9, 2020

From Title 28-JUDICIARY AND JUDICIAL PROCEDURE
PART IV-JURISDICTION AND VENUE
CHAPTER 81-SUPREME COURT
Jump To:

§1254. Courts of appeals; certiorari; certified questions

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

(1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;

(2) By certification at any time by a court of appeals of any question of law in any civil or criminal case as to which instructions are desired, and upon such certification the Supreme Court may give binding instructions or require the entire record to be sent up for decision of the entire matter in controversy.

(June 25, 1948, ch. 646, 62 Stat. 928 ; Pub. L. 100–352, §2(a), (b), June 27, 1988, 102 Stat. 662 .)

Historical and Revision Notes

Based on title 28, U.S.C., 1940 ed., §§346 and 347 (Mar. 3, 1911, ch. 231, §§239, 240, 36 Stat. 1157 ; Feb. 13, 1925, ch. 229, §1, 43 Stat. 938 ; Jan. 31, 1928, ch. 14, §1, 45 Stat. 54 ; June 7, 1934, ch. 426, 48 Stat. 926).

Section consolidates sections 346 and 347 of title 28, U.S.C., 1940 ed.

Words "or in the United States Court of Appeals for the District of Columbia" and "or of the United States Court of Appeals for the District of Columbia" in sections 346 and 347 of title 28, U.S.C., 1940 ed., were omitted. (See section 41 of this title.)

The prefatory words of this section preceding paragraph (1) were substituted for subsection (c) of said section 347.

The revised section omits the words of section 347 of title 28, U.S.C., 1940 ed., "and with like effect as if the case had been brought there with unrestricted appeal", and the words of section 346 of such title "in the same manner as if it had been brought there by appeal". The effect of subsections (1) and (3) of the revised section is to preserve existing law and retain the power of unrestricted review of cases certified or brought up on certiorari. Only in subsection (2) is review restricted.

Changes were made in phraseology and arrangement.

Amendments

1988-Pub. L. 100–352, §2(b), struck out "appeal;" after "certiorari;" in section catchline.

Pars. (2), (3). Pub. L. 100–352, §2(a), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: "By appeal by a party relying on a State statute held by a court of appeals to be invalid as repugnant to the Constitution, treaties or laws of the United States, but such appeal shall preclude review by writ of certiorari at the instance of such appellant, and the review on appeal shall be restricted to the Federal questions presented;".

Effective Date of 1988 Amendment

Pub. L. 100–352, §7, June 27, 1988, 102 Stat. 664 , provided that: "The amendments made by this Act [amending sections 1254, 1257, 1258, 2101, 2104, and 2350 of this title, section 136w of Title 7, Agriculture, section 1631e of Title 22, Foreign Relations and Intercourse, section 652 of Title 25, Indians, section 988 of Title 33, Navigation and Navigable Waters, section 1652 of Title 43, Public Lands, sections 719, 743, and 1105 of Title 45, Railroads, and section 30110 of Title 52, Voting and

Elections, and repealing sections 1252 and 2103 of this title] shall take effect ninety days after the date of the enactment of this Act [June 27, 1988], except that such amendments shall not apply to cases pending in the Supreme Court on the effective date of such amendments or affect the right to review or the manner of reviewing the judgment or decree of a court which was entered before such effective date."

42 USC 1395: Prohibition against any Federal interference
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Jump To:

§1395. Prohibition against any Federal interference

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

(Aug. 14, 1935, ch. 531, title XVIII, §1801, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 291 .)

SHORT TITLE

For short title of title I of Pub. L. 89–97, which enacted this subchapter as the "Health Insurance for the Aged Act", see section 100 of Pub. L. 89–97, set out as a Short Title of 1965 Amendment note under section 1305 of this title.

PROTECTING AND IMPROVING GUARANTEED MEDICARE BENEFITS

Pub. L. 111–148, title III, §3601, Mar. 23, 2010, 124 Stat. 538 , provided that:

"(a) PROTECTING GUARANTEED MEDICARE BENEFITS.-Nothing in the provisions of, or amendments made by, this Act [see Short Title note set out under section 18001 of this title] shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

"(b) ENSURING THAT MEDICARE SAVINGS BENEFIT THE MEDICARE PROGRAM AND MEDICARE BENEFICIARIES.-Savings generated for the Medicare program under title XVIII of the Social Security Act under the provisions of, and amendments made by, this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers."

42 USC 1395f: Conditions of and limitations on payment for services
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part A-Hospital Insurance Benefits for Aged and Disabled

Jump To:

§1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if-

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner, a clinical nurse specialist, or a physician assistant (as those terms are defined in section 1395x(aa)(5) of this title) who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,,[1] or, in the case of services described in subparagraph (C), a physician, a nurse practitioner or clinical nurse specialist (as such terms are defined in section 1395x(aa)(5) of this title) who is working in accordance with State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) who is working in accordance with State law, who is enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that-

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in

the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, a nurse practitioner, a clinical nurse specialist, or a physician assistant (as the case may be); such services are or were furnished while the individual was under the care of a physician, a nurse practitioner, a clinical nurse specialist, or a physician assistant (as the case may be), and, in the case of a certification made by a physician after January 1, 2010, or by a nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) after a date specified by the Secretary (but in no case later than the date that is 6 months after March 27, 2020), prior to making such certification a physician, nurse practitioner, clinical nurse specialist, or physician assistant must document that a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or physician assistant has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1395m(m) of this title, and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services, there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1395cc(d) of this title (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1395x(k)(4) of this title, including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the day on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual-

(A)(i) in the first 90-day period-

(I) the individual's attending physician (as defined in section 1395x(dd)(3)(B) of this title) (which for purposes of this subparagraph does not include a nurse practitioner or a physician assistant), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care,

each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program;

(C) such care is being or was provided pursuant to such plan of care;

(D) on and after January 1, 2011 (and, in the case of clause (ii), before October 6, 2014)-

(i)(I) subject to subclause (II), a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary); and

(II) during the emergency period described in section 1320b–5(g)(1)(B) of this title, a hospice physician or nurse practitioner may conduct a face-to-face encounter required under this clause via telehealth, as determined appropriate by the Secretary; and

(ii) in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of such cases for all programs under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(E) on and after October 6, 2014, in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of all cases of individuals provided hospice care by the program under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981 (or in the case of regulations to implement the amendments made by section 3708 of the CARES Act, the Secretary shall prescribe regulations, which shall become effective no later than 6 months after March 27, 2020), and which prohibit a physician, nurse practitioner, clinical nurse specialist, or physician assistant who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician, nurse practitioner, clinical nurse specialist, or physician assistant as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of documentation for physician certification and recertification made under paragraph (2) on or after January 1, 2019 or no later than 6 months after March 27, 2020, for purposes of documentation for certification and recertification made under paragraph (2) by a nurse practitioner, clinical nurse specialist, or physician assistant,,[1] and made with respect to home health services furnished by a home health agency, in addition to using documentation in the medical record of the physician, nurse practitioner, clinical nurse specialist, or physician assistant who so certifies or the medical record of the acute or post-acute care facility (in the case that home health services were furnished to an individual who was directly admitted to the home health agency from such a facility), the Secretary may use documentation in the medical record of the home health agency as supporting material, as appropriate to the case involved. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or

medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

(b) Amount paid to provider of services

The amount paid to any provider of services (other than a hospice program providing hospice care, other than a critical access hospital providing inpatient critical access hospital services, and other than a home health agency with respect to durable medical equipment) with respect to services for which payment may be made under this part shall, subject to the provisions of sections 1395e, 1395ww, and 1395fff of this title, be-

(1) except as provided in paragraph (3), the lesser of (A) the reasonable cost of such services, as determined under section 1395x(v) of this title and as further limited by section 1395rr(b)(2)(B) of this title, or (B) the customary charges with respect to such services;

(2) if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this paragraph), free of charge or at nominal charges to the public, the amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such reasonable cost which the Secretary finds will provide fair compensation to such provider for such services; or

(3) if some or all of the hospitals in a State have been reimbursed for services (for which payment may be made under this part) pursuant to a reimbursement system approved as a demonstration project under section 402 of the Social Security Amendments of 1967 or section 222 of the Social Security Amendments of 1972, if the rate of increase in such hospitals in their costs per hospital inpatient admission of individuals entitled to benefits under this part over the duration of such project was equal to or less than such rate of increase for admissions of such individuals with respect to all hospitals in the United States during such period, and if either the State has legislative authority to operate such system and the State elects to have reimbursement to such hospitals made in accordance with this paragraph or the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to those hospitals made in accordance with this paragraph, then, subject to section 1395ww(d)(3)(B)(ix)(III) [2] of this title, the Secretary may provide for continuation of reimbursement to such hospitals under such system until the Secretary determines that-

(A) a third-party payor reimburses such a hospital on a basis other than under such system, or

(B) the aggregate rate of increase from January 1, 1981, to the most recent date for which annual data are available in such hospitals in costs per hospital inpatient admission of individuals entitled to benefits under this part is greater than such rate of increase for admissions of such individuals with respect to all hospitals in the United States for such period.

In the case of any State which has had such a demonstration project reimbursement system in continuous operation since July 1, 1977, the Secretary shall provide under paragraph (3) for continuation of reimbursement to hospitals in the State under such system until the first day of the 37th month beginning after the date the Secretary determines and notifies the Governor of the State that either of the conditions described in subparagraph (A) or (B) of such paragraph has occurred. If, by the end of such 36-month period, the Secretary determines, based on evidence submitted by the Governor of the State, that neither of the conditions described in subparagraph (A) or (B) of paragraph (3) continues to apply, the Secretary shall continue without interruption payment to hospitals in the State under the State's system. If, by the end of such 36-month period, the Secretary determines, based on such evidence, that either of the conditions described in subparagraph (A) or (B) of such paragraph continues to apply, the Secretary shall (i) collect any net excess reimbursement to hospitals in the State during such 36-month period (basing such net excess reimbursement on the net difference, if any, in the rate of increase in costs per hospital inpatient admission under the State system compared to the rate of increase in such costs with respect to all hospitals in the United States over the 36-month period, as measured by including the cumulative savings under the State system based on the difference in the rate of increase in costs per hospital inpatient admission under the State system as compared to the rate of increase in such costs with respect to all hospitals in the United States between January 1, 1981, and the date of the Secretary's initial notice), and (ii) provide a reasonable period, not to exceed 2 years, for transition from the State system to the national payment system. For purposes of applying paragraph (3), there shall be taken into account incentive payments, and payment adjustments under subsection (b)(3)(B)(ix) or (n) of section 1395ww of this title.

42 USC 1395h: Provisions relating to the administration of part A
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part A-Hospital Insurance Benefits for Aged and Disabled

Jump To:

§1395h. Provisions relating to the administration of part A

(a) In general

The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk–1 of this title.

(b) Repealed. Pub. L. 108–173, title IX, §911(b)(3), Dec. 8, 2003, 117 Stat. 2383

(c) Prompt payment of claims

(1) Repealed. Pub. L. 108–173, title IX, §911(b)(4)(A), Dec. 8, 2003, 117 Stat. 2383 .

(2)(A) Each contract under section 1395kk–1 of this title that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this subchapter-

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this subchapter.

(ii) The term "applicable number of calendar days" means-

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days,

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days,

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days, and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received from a hospital, critical access hospital, skilled nursing facility, home health agency, hospice program, comprehensive outpatient rehabilitation facility, or rehabilitation agency that is not receiving payments on a periodic interim payment basis with respect to such services, interest shall be paid at the rate used for purposes of section 3902(a) of title 31 (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)(A) Each contract under section 1395kk–1 of this title that provides for making payments under this part shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any

claim submitted under this subchapter within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term "applicable number of calendar days" means-

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

(d) to (i). Repealed. Pub. L. 108–173, title IX, §911(b)(5), Dec. 8, 2003, 117 Stat. 2383

(j) Denial of claim; notification and reconsideration

A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to such medicare administrative contractor that is denied, such medicare administrative contractor-

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial, promptly notify such individual and the provider of the disposition of such reconsideration.

(k) Annual reporting requirement on erroneous payment recovery

A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part shall require that such medicare administrative contractor submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1395y(b)(2)(A) of this title).

(l) Repealed. Pub. L. 108–173, title IX, §911(b)(7), Dec. 8, 2003, 117 Stat. 2383

(Aug. 14, 1935, ch. 531, title XVIII, §1816, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 297 ; amended Pub. L. 92–603, title II, §243(b), Oct. 30, 1972, 86 Stat. 1422 ; Pub. L. 95–142, §14(a), Oct. 25, 1977, 91 Stat. 1198 ; Pub. L. 96–499, title IX, §930(o), Dec. 5, 1980, 94 Stat. 2632 ; Pub. L. 97–248, title I, §122(c)(3), Sept. 3, 1982, 96 Stat. 359 ; Pub. L. 98–369, div. B, title III, §2326(b), (c)(1), (d)(1), July 18, 1984, 98 Stat. 1087 ; Pub. L. 99–509, title IX, §§9311(b), 9352(a)(2), Oct. 21, 1986, 100 Stat. 1997 , 2044; Pub. L. 100–203, title IV, §§4031(a)(1), 4032(a), (b), 4035(a)(1), 4085(d)(1), Dec. 22, 1987, 101 Stat. 1330–75 to 1330-78, 1330-130; Pub. L. 100–360, title II, §203(f), title IV, §411(e)(1)(B), July 1, 1988, 102 Stat. 725 , 775; Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981 ; Pub. L. 101–239, title VI, §§6003(g)(3)(D)(vi), 6202(d)(1), Dec. 19, 1989, 103 Stat. 2153 , 2234; Pub. L. 101–508, title IV, §4005(c)(1)(A), Nov. 5, 1990, 104 Stat. 1388–41 ; Pub. L. 103–66, title XIII, §13568(a), (b), Aug. 10, 1993, 107 Stat. 608 ; Pub. L. 103–432, title I, §§110(d)(2), 151(b)(1)(A), (2)(A), Oct. 31, 1994, 108 Stat. 4408 , 4433, 4434; Pub. L. 104–191, title II, §202(b)(1), Aug. 21, 1996, 110 Stat. 1998 ; Pub. L. 105–33, title IV, §4201(c)(1), Aug. 5, 1997, 111 Stat. 373 ; Pub. L. 108–173, title VII, §736(a)(4), title IX, §911(b), Dec. 8, 2003, 117 Stat. 2355 , 2383; Pub. L. 109–171, title V, §5202(a)(1), Feb. 8, 2006, 120 Stat. 47 .)

AMENDMENTS

2006-Subsec. (c)(3)(B)(ii). Pub. L. 109–171 substituted "28 days" for "26 days".

2003-Pub. L. 108–173, §911(b)(1), substituted "Provisions relating to the administration of part A" for "Use of public or private agencies or organizations to facilitate payment to providers of services" in section catchline.

Subsec. (a). Pub. L. 108–173, §911(b)(2), amended subsec. (a) generally. Prior to amendment, subsec. (a) authorized Secretary to enter into agreements with agencies or organizations to determine and pay amounts under this part.

Subsec. (b). Pub. L. 108–173, §911(b)(3), struck out subsec. (b), which set forth prerequisites for agreement or renewal of agreement.

Subsec. (c)(1). Pub. L. 108–173, §911(b)(4)(A), struck out par. (1), which related to terms and conditions of agreements.

Subsec. (c)(2)(A). Pub. L. 108–173, §911(b)(4)(B), substituted "contract under section 1395kk–1 of this title that provides for making payments under this part" for "agreement under this section" in introductory provisions.

Subsec. (c)(2)(B)(ii)(III). Pub. L. 108–173, §736(a)(4)(A), struck out "and" at end.

Subsec. (c)(2)(B)(ii)(IV). Pub. L. 108–173, §736(a)(4)(B), substituted ", and" for period at end.

Subsec. (c)(3)(A). Pub. L. 108–173, §911(b)(4)(B), substituted "contract under section 1395kk–1 of this title that provides for making payments under this part" for "agreement under this section".

Subsecs. (d) to (i). Pub. L. 108–173, §911(b)(5), struck out subsecs. (d) to (i), which related to nomination of agency or organization, designation of agency or organization to perform provider services, standards, criteria, and procedures for evaluation of agency or organization performance, termination of agreement, bonding requirement for officers and employees, and liability of certifying and disbursing officers.

Subsec. (j). Pub. L. 108–173, §911(b)(6), in introductory provisions, substituted "A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part" for "An agreement with an agency or organization under this section" and "such medicare administrative contractor" for "such agency or organization" in two places.

Subsec. (k). Pub. L. 108–173, §911(b)(6), substituted "A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part" for "An agreement with an agency or organization under this section" and "such medicare administrative contractor" for "such agency or organization".

Subsec. (l). Pub. L. 108–173, §911(b)(7), struck out subsec. (l), which prohibited any activity pursuant to an agreement under this section that is carried out pursuant to a contract under the Medicare Integrity Program.

1997-Subsec. (c)(2)(C). Pub. L. 105–33 substituted "critical access" for "rural primary care".

1996-Subsec. (l). Pub. L. 104–191 added subsec. (l).

1994-Subsec. (f)(1)(A). Pub. L. 103–432, §151(b)(2)(A), inserted "(including the agency's or organization's success in recovering payments made under this subchapter for services for which payment has been or could be made under a primary plan (as defined in section 1395y(b)(2)(A) of this title))" after "processing".

Subsec. (f)(2)(A)(ii). Pub. L. 103–432, §110(d)(2), substituted "such agency's" for "such agency".

Subsec. (k). Pub. L. 103–432, §151(b)(1)(A), added subsec. (k).

1993-Subsec. (c)(2)(B)(ii)(IV), (V). Pub. L. 103–66, §13568(b), substituted "period ending on or before September 30, 1993" for "period" in subcl. (IV) and added subcl. (V).

Subsec. (c)(3)(B). Pub. L. 103–66, §13568(a), added cls. (i) and (ii) and struck out former cls. (i) and (ii) which read as follows:

"(i) with respect to claims received in the 3-month period beginning July 1, 1988, 10 days, and

"(ii) with respect to claims received in the 12-month period beginning October 1, 1988, 14 days."

1990-Subsec. (f). Pub. L. 101–508 designated existing provisions as par. (1), redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, struck out "Such standards and criteria" and all that follows, which was executed by striking out "Such standards and criteria shall be published in the Federal Register, and opportunity shall be provided for public comment prior to implementation. Such standards and criteria shall include with respect to claims for services furnished under this part by any provider of services other than a hospital whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of the fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days and the extent to which its determinations are reversed on appeal.", and added par. (2).

1989-Subsec. (c)(1). Pub. L. 101–239, §6202(d)(1), inserted at end "The Secretary may not require, as a condition of entering into or renewing an agreement under this section or under section 1395hh of this title, that a fiscal intermediary match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which the provisions of section 1395y(b) of this title may apply."

Subsec. (c)(2)(C). Pub. L. 101–239, §6003(g)(3)(D)(vi), inserted "rural primary care hospital," after "hospital,".

Subsec. (k). Pub. L. 101–234 repealed Pub. L. 100–360, §203(f), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

1988-Subsec. (j)(2). Pub. L. 100–360, §411(e)(1)(B), inserted "in the case of a request for reconsideration of a denial," and substituted "the disposition" for "disposition".

Subsec. (k). Pub. L. 100–360, §203(f), added subsec. (k) relating to use of regional intermediaries in administration of benefits.

1987-Subsec. (c)(1). Pub. L. 100–203, §4035(a)(1), inserted at end "The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for fiscal intermediaries under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used."

Subsec. (c)(2)(C). Pub. L. 100–203, §4085(d)(1), substituted "hospice program, comprehensive outpatient rehabilitation facility, or rehabilitation agency" for "or hospice program".

Subsec. (c)(3). Pub. L. 100–203, §4031(a)(1), added par. (3).

Subsec. (f). Pub. L. 100–203, §4023(b), inserted at end "Such standards and criteria shall include with respect to claims for services furnished under this part by any provider of services other than a hospital whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of the fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days and the extent to which its determinations are reversed on appeal."

Subsec. (j). Pub. L. 100–203, §4032(a), added subsec. (j).

1986-Subsec. (a). Pub. L. 99–509, §9352(a)(2), inserted at end "As used in this subchapter and part B of subchapter XI of this chapter, the term 'fiscal intermediary' means an agency or organization with a contract under this section."

Subsec. (c). Pub. L. 99–509, §9311(b), designated existing provisions as par. (1) and added par. (2).

1984-Subsec. (c). Pub. L. 98–369, §2326(d)(1), inserted provision that the Secretary, in determining the necessary and proper cost of administration with respect to each agreement, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated agency or organization in carrying out the terms of its agreement.

Subsec. (e)(4). Pub. L. 98–369, §2326(b), inserted provision that not later than July 1, 1987, the Secretary limit the number of regional agencies or organizations to not more than ten.

Subsec. (f). Pub. L. 98–369, §2326(c)(1), struck out in cl. (2) ", by regulation," after "Secretary shall establish" and inserted provision that the standards and criteria be published in the Federal Register and an opportunity be provided for public comment prior to implementation.

1982-Subsec. (e)(5). Pub. L. 97–248 added par. (5).

1980-Subsec. (e)(2). Pub. L. 96–499, §930(o)(1), inserted "(subject to the provisions of paragraph (4))".

Subsec. (e)(4). Pub. L. 96–499, §930(o)(2), added par. (4).

1977-Subsec. (a). Pub. L. 95–142, §14(a)(1), inserted provisions relating to applicability to providers assigned to the agency or organization under subsec. (e) of this section.

Subsec. (b). Pub. L. 95–142, §14(a)(2), substituted provisions setting forth criteria for agreements by the Secretary or renewal of such agreements with agencies or organizations, for provisions setting forth criteria for agreements by the Secretary with agencies or organizations.

Subsecs. (e), (f). Pub. L. 95–142, §14(a)(4), (5), added subsecs. (e) and (f). Former subsecs. (e) and (f) redesignated (g) and (h), respectively.

Subsec. (g). Pub. L. 95–142, §14(a)(3), (4), redesignated former subsec. (e) as (g) and inserted provisions relating to applicability of standards, etc., developed under subsec. (f) of this section. Former subsec. (g) redesignated (i).

Subsecs. (h), (i). Pub. L. 95–142, §14(a)(4), redesignated former subsecs. (f) and (g) as (h) and (i), respectively.

1972-Subsec. (a). Pub. L. 92–603 inserted reference to provisions of section 1395oo of this title.

Effective Date of 2006 Amendment

Pub. L. 109–171, title V, §5202(b), Feb. 8, 2006, 120 Stat. 47 , provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to claims submitted on or after January 1, 2006."

Effective Date of 2003 Amendment

Amendment by section 911(b) of Pub. L. 108–173 effective Oct. 1, 2005, except as otherwise provided, with transition rules authorizing Secretary of Health and Human Services to continue to enter into agreements under this section prior to such date, and provisions authorizing continuation of Medicare Integrity Program functions during the period that begins on Dec. 8, 2003, and ends on Oct. 1, 2011, see section 911(d) of Pub. L. 108–173, set out as an Effective Date; Transition Rule note under section 1395kk–1 of this title.

Effective Date of 1997 Amendment

Amendment by Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Effective Date of 1994 Amendment

Pub. L. 103–432, title I, §151(b)(4), Oct. 31, 1994, 108 Stat. 4435 , provided that: "The amendments made by paragraphs (1) and (2) [amending this section and section 1395u of this title] shall apply to contracts with fiscal intermediaries and carriers under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for contract years beginning with 1995."

Effective Date of 1993 Amendment

Pub. L. 103–66, title XIII, §13568(c), Aug. 10, 1993, 107 Stat. 608 , provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to claims received on or after October 1, 1993."

Effective Date of 1989 Amendment

Pub. L. 101–239, title VI, §6202(d)(3), Dec. 19, 1989, 103 Stat. 2234 , provided that: "The amendments made by this subsection [amending this section and section 1395u of this title] shall apply to agreements and contracts entered into or renewed on or after the date of the enactment of this Act [Dec. 19, 1989]."

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

Effective Date of 1988 Amendment

Amendment by section 203(f) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(e)(1)(B) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date of 1987 Amendment

Pub. L. 100–203, title IV, §4031(a)(3)(A), Dec. 22, 1987, 101 Stat. 1330–76 , provided that: "The amendments made by paragraphs (1) and (2) [amending this section and section 1395u of this title] shall apply to claims received on or after July 1, 1988."

Pub. L. 100–203, title IV, §4032(c)(1), Dec. 22, 1987, 101 Stat. 1330–77 , as amended by Pub. L. 100–360, title IV, §411(e)(1)(C), July 1, 1988, 102 Stat. 775 , provided that:

"(A) The amendment made by subsection (a) [amending this section] shall apply with respect to claims received on or after January 1, 1988.

"(B) The amendment made by subsection (b) [amending this section] shall apply with respect to reconsiderations requested on or after October 1, 1988."

Pub. L. 100–203, title IV, §4035(a)(3), Dec. 22, 1987, 101 Stat. 1330–78 , provided that: "The amendments made by this section [amending this section and sections 1395u and 1395hh of this title] shall take effect on the date of the enactment of this Act [Dec. 22, 1987] and shall apply to budgets for fiscal years beginning with fiscal year 1989."

Pub. L. 100–203, title IV, §4085(d)(2), Dec. 22, 1987, 101 Stat. 1330–131 , provided that:

"(A) The amendment made by paragraph (1) [amending this section] shall apply to claims received on or after the date of enactment of this Act [Dec. 22, 1987].

"(B) The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 [42 U.S.C. 1395h], and regulations, to such extent as may be necessary to implement the amendment made by paragraph (1)."

Effective Date of 1986 Amendment

Pub. L. 99–509, title IX, §9311(d), Oct. 21, 1986, 100 Stat. 1999 , provided that:

"(1) Except as provided in paragraph (2), the amendments made by subsections (b) and (c) [amending this section and section 1395u of this title] shall apply to claims received on or after November 1, 1986.

"(2) Sections 1816(c)(2)(C)) [sic] and 1842(c)(2)(C) of the Social Security Act [42 U.S.C. 1395h(c)(2)(C), 1395u(c)(2)(C)], as added by such amendments, shall apply to claims received on or after April 1, 1987.

"(3) The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 of the Social Security Act [42 U.S.C. 1395h] and contracts under section 1842 of such Act [42 U.S.C. 1395u], and regulations, to such extent as may be necessary to implement the provisions of this Act on a timely basis."

Amendment by section 9352(a)(2) of Pub. L. 99–509 to be implemented by Secretary of Health and Human Services not later than 6 months after Oct. 21, 1986, see section 9352(c)(1) of Pub. L. 99–509, set out as a note under section 1320c–2 of this title.

Effective Date of 1984 Amendment

Pub. L. 98–369, div. B, title III, §2326(d)(3), July 18, 1984, 98 Stat. 1088 , provided that: "The amendments made by this subsection [amending this section and section 1395u of this title] shall apply to agreements and contracts entered into or renewed after September 30, 1984."

Effective Date of 1982 Amendment

Amendment by Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.

Effective Date of 1980 Amendment

Amendment by Pub. L. 96–499 effective Dec. 5, 1980, see section 930(s)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Effective Date of 1977 Amendment

Pub. L. 95–142, §14(c), (d), Oct. 25, 1977, 91 Stat. 1200 , provided that:

"(c) The amendment made by paragraphs (2) and (3) of subsection (a) [amending this section] to the extent that they require application of standards, criteria, and procedures developed under section 1816(f) of the Social Security Act [42 U.S.C. 1395h(f)] shall apply to the entering into, renewal, or termination of agreements on and after October 1, 1978.

"(d) Except as provided in subsection (c), the amendment made by subsection (a)(2) [amending this section] shall apply to agreements entered into or renewed on or after the date of enactment of this Act [Oct. 25, 1977]."

Effective Date of 1972 Amendment

Amendment by Pub. L. 92–603 applicable with respect to cost reports of providers of services for accounting periods ending on or after June 30, 1973, see section 243(c) of Pub. L. 92–603, set out as an Effective Date note under section 1395oo of this title.

Advisory Committee on Medicare Home Health Claims

Pub. L. 100–360, title IV, §427, July 1, 1988, 102 Stat. 814 , which provided that the Administrator of the Health Care Financing Administration was to establish an advisory committee to be known as the Advisory Committee on Medicare Home Health Claims to study the reasons for the increase in the denial of claims for home health services during 1986 and 1987, the ramifications of such increase, and the need to reform the process involved in such denials, was repealed by Pub. L. 101–234, title III, §301(a), Dec. 13, 1989, 103 Stat. 1985 .

Amendments to Agreements and Contracts Necessary To Implement Section 4031(a) of Pub. L. 100–203

Pub. L. 100–203, title IV, §4031(a)(3)(B), Dec. 22, 1987, 101 Stat. 1330–76 , provided that: "The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 of the Social Security Act [42 U.S.C. 1395h] and contracts under section 1842 of such Act [42 U.S.C. 1395u], and regulations, to such extent as may be necessary to implement the provisions of this subsection [amending this section and section 1395u of this title] on a timely basis."

Prohibition of Policies Other Than as Provided by Section 4031 of Pub. L. 100–203 Intended To Slow Down Medicare Payments; Budget Considerations

Pub. L. 100–203, title IV, §4031(b), (c), Dec. 22, 1987, 101 Stat. 1330–76 , provided that, notwithstanding any other provision of law, the Secretary of Health and Human Services was not authorized to issue, after Dec. 22, 1987, and before Oct. 1, 1990, any final regulation, instruction, or other policy change which was primarily intended to have the effect of slowing down claims processing, or delaying payment of claims, under this subchapter, and that section 4031 of Pub. L. 100–203, amending this section and section 1395u of this title and enacting provisions set out as notes under this section, was a necessary (but secondary) result of a significant policy change.

Amendments to Agreements and Contracts Necessary To Implement Section 4032(a), (b) of Pub. L. 100–203

Pub. L. 100–203, title IV, §4032(c)(2), Dec. 22, 1987, 101 Stat. 1330–77 , provided that: "The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 [42 U.S.C. 1395h] and contracts under section 1842 of the Social Security Act [42 U.S.C. 1395u], and regulations, to such extent as may be necessary to implement the amendments made by subsections (a) and (b) [amending this section] on a timely basis."

Replacement of Agency, Organization, or Carrier Processing Medicare Claims; Number of Agreements and Contracts Authorized for Fiscal Years 1985 Through 1993

Pub. L. 98–369, div. B, title III, §2326(a), July 18, 1984, 98 Stat. 1087 , as amended by Pub. L. 98–617, §3(a)(2), Nov. 8, 1984, 98 Stat. 3295 ; Pub. L. 99–509, title IX, §9321(b), Oct. 21, 1986, 100 Stat. 2016 ; Pub. L. 101–239, title VI, §6215(a), Dec. 19, 1989, 103 Stat. 2252 ; Pub. L. 103–432,

title I, §159(a), Oct. 31, 1994, 108 Stat. 4443 , provided that: "During each fiscal year (beginning with fiscal year 1985 and ending with fiscal year 1993), the Secretary of Health and Human Services may enter into not more than two agreements under section 1816 of the Social Security Act [42 U.S.C. 1395h], and not more than two contracts under section 1842 of such Act [42 U.S.C. 1395u], on the basis of competitive bidding, without regard to the nominating process under section 1816(a) of such Act or cost reimbursement provisions under sections 1816(c) or 1842(c) of such Act during the term of the agreement. Such procedure may be used only for the purpose of replacing an agency or organization or carrier which over a 2-year period of time has been in the lowest 20th percentile of agencies and organizations or carriers having agreements or contracts under the respective section, as measured by the Secretary's cost and performance criteria. In addition, beginning with fiscal year 1990 and any subsequent fiscal year the Secretary may enter into such additional agreements and contracts without regard to such cost reimbursement provisions if the fiscal intermediary or carrier involved and the Secretary agree to waive such provisions, but the Secretary may not take any action that has the effect of requiring that the intermediary or carrier agree to waive such provisions, including requiring such a waiver as a condition for entering into or renewing such an agreement or contract. Any agency or organization or carrier selected on the basis of competitive bidding must perform all of the duties listed in section 1816(a) of such Act, or the duties listed in paragraphs (1) through (4) of section 1842(a) of such Act, as the case may be, and must be a health insuring organization (as determined by the Secretary)."

[Pub. L. 103–432, title I, §159(b), Oct. 31, 1994, 108 Stat. 4443 , provided that: "The amendment made by subsection (a) [amending section 2326(a) of Pub. L. 98–369, set out above] shall apply beginning with fiscal year 1994."]

[Pub. L. 101–239, title VI, §6215(b), Dec. 19, 1989, 103 Stat. 2252 , provided that: "The amendments made by subsection (a) [amending section 2326(a) of Pub. L. 98–369, set out above] shall apply beginning with fiscal year 1990."]

Audit and Medical Claims Review

Pub. L. 97–248, title I, §118, Sept. 3, 1982, 96 Stat. 355 , as amended by Pub. L. 99–272, title IX, §9216(a), Apr. 7, 1986, 100 Stat. 180 , provided that, in addition to any funds otherwise provided for payments to intermediaries and carriers under agreements entered into under this section and section 1395u of this title, there were transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Fund an additional $45,000,000 for each of fiscal years 1983, 1984, and 1985, and $105,000,000 for each of fiscal years 1986, 1987, and 1988 for payments to such intermediaries and carriers under such agreements to be used exclusively for purposes of carrying out provider cost audits, of reviewing medical necessity, and of recovering third-party liability payments.

Developmental Date for Standards, Criteria, and Procedures Pursuant to Subsec. (f) of This Section

Pub. L. 95–142, §14(b), Oct. 15, 1977, 91 Stat. 1200 , directed the Secretary of Health, Education, and Welfare to develop the standards, criteria, and procedures described in subsection (f) of section 1816 of the Social Security Act [42 U.S.C. 1395h(f)] (as added by subsection (a)(5)) not later than Oct. 1, 1978.

42 USC 1395u: Provisions relating to the administration of part B
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part B-Supplementary Medical Insurance Benefits for Aged and Disabled

Jump To:

§1395u. Provisions relating to the administration of part B

(a) In general

The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk–1 of this title.

(b) Determination of reasonable charges

(1) Repealed. Pub. L. 108–173, title IX, §911(c)(3)(A), Dec. 8, 2003, 117 Stat. 2384 .

(2)(A), (B) Repealed. Pub. L. 108–173, title IX, §911(c)(3)(B)(i), Dec. 8, 2003, 117 Stat. 2384 .

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1395x(s)(2)(K) of this title performed by a member of a team, the Secretary shall instruct medicare administrative contractors to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

(3) The Secretary-

(A) shall take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1395x(v) of this title);

(B) shall take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1395gg(f) of this title) be made-

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this subchapter is denied under section 1320c–3(a)(2) of this title by reason of a determination under section 1320c–3(a)(1)(B) of this title, and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1395y(a) of this title, and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter (except in the case of physicians' services and ambulance service furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title);

42 USC 1395y: Exclusions from coverage and medicare as secondary payer
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part E-Miscellaneous Provisions

Jump To:

§1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services-

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,[1]

(E) in the case of research conducted pursuant to section 1320b–12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title, and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(oo) of this title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1395m(d) of this title,

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1395w–3a(c)(6)(C) of this title for which payment is made under part B that is furnished in a competitive area under section 1395w–3b of this title, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

42 USC 1395ff: Determinations; appeals
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part E-Miscellaneous Provisions

Jump To:

§1395ff. Determinations; appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A or part B in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1320c–3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w–22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI.

(2) Deadlines for making initial determinations

(A) In general

Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims

Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general

In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations

(i) Appeal rights

No initial determination may be reconsidered or appealed under subsection (b) unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker

No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines

(i) Filing for redetermination

A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations

Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction

For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations

With respect to an initial determination insofar as it results in a denial of a claim for benefits-

(A) the written notice on the determination shall include-

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations

With respect to a redetermination insofar as it results in a denial of a claim for benefits-

(A) the written notice on the redetermination shall include-

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights

(1) In general

(A) Reconsideration of initial determination

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 405 of this title shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) Representation by provider or supplier

(i) In general

Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary

Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation

If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary

The provisions of section 405(j) of this title and of section 406 of this title (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment

The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals

(i) Reconsiderations

Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3), or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary

The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 405 and 406 of this title.

(E) Amounts in controversy

(i) In general

A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.

(ii) Aggregation of claims

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve-

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts

For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(F) Expedited proceedings

(i) Expedited determination

In the case of an individual who has received notice from a provider of services that such provider plans-

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1), as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review

For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review

(A) In general

The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations

If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review

(i) In general

If the appropriate review entity-

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B),

then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing

Such action shall be filed, in the case described in-

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue

Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy

Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this subchapter.

(D) Review entity defined

For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers

A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors

(1) In general

The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1). Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor

For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1), and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements

Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general

The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations

(i) In general

The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations

(I) National coverage determinations

If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1395y(a) of this title, such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations

If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination

In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions

(i) Reconsiderations

Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline

In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) Expedited reconsiderations

The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) as follows:

(I) Deadline for decision

Notwithstanding section 416(j) of this title and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary

In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges

A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1320c–3(e) of this title as in effect on the date that precedes December 21, 2000.

(iv) Extension

An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers

The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision

Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate) and shall include 1

a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and [2] a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section [3] and [3] in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title) [3] an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements

Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A or part B of such decision.

(G) Dissemination of decisions on reconsiderations

Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1395h of this title), carriers (under section 1395u of this title), quality improvement organizations (under part B of subchapter XI), Medicare+Choice organizations offering Medicare+Choice plans under part C, other entities under contract with the Secretary to make initial determinations under part A or part B or subchapter XI, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) Ensuring consistency in decisions

Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection

(i) In general

Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected

Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting

Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary

The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements

(i) In general

Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity-

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation

Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation

Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors

The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability

No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice

(1) Hearing by administrative law judge

(A) In general

Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) Waiver of deadline by party seeking hearing

The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review

(A) In general

The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure

In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines

(A) Hearing by administrative law judge

In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) Departmental Appeals Board review

In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) Notice

Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include-

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(e) Administrative provisions

(1) Limitation on review of certain regulations

A regulation or instruction that relates to a method for determining the amount of payment under part B and that was initially issued before January 1, 1981, shall not be subject to judicial review.

(2) Outreach

The Secretary shall perform such outreach activities as are necessary to inform individuals entitled to benefits under this subchapter and providers of services and suppliers with respect to their rights of, and the process for, appeals made under this section. The Secretary shall use the toll-free telephone number maintained by the Secretary under section 1395b–2(b) of this title to provide information regarding appeal rights and respond to inquiries regarding the status of appeals.

(3) Continuing education requirement for qualified independent contractors and administrative law judges

The Secretary shall provide to each qualified independent contractor, and, in consultation with the Commissioner of Social Security, to administrative law judges that decide appeals of reconsiderations of initial determinations or other decisions or determinations under this section, such continuing education with respect to coverage of items and services under this subchapter or policies of the Secretary with respect to part B of subchapter XI as is necessary for such qualified independent contractors and administrative law judges to make informed decisions with respect to appeals.

(4) Reports

(A) Annual report to Congress

The Secretary shall submit to Congress an annual report describing the number of appeals for the previous year, identifying issues that require administrative or legislative actions, and including any recommendations of the Secretary with respect to such actions. The Secretary shall include in such report an analysis of determinations by qualified independent contractors with respect to inconsistent decisions and an analysis of the causes of any such inconsistencies.

(B) Survey

Not less frequently than every 5 years, the Secretary shall conduct a survey of a valid sample of individuals entitled to benefits under this subchapter who have filed appeals of determinations under this section, providers of services, and suppliers to determine the satisfaction of such individuals or entities with the process for appeals of determinations provided for under this section and education and training provided by the Secretary with respect to that process. The Secretary shall submit to Congress a report describing the results of the survey, and shall include any recommendations for administrative or legislative actions that the Secretary determines appropriate.

(f) Review of coverage determinations

(1) National coverage determinations

(A) In general

Review of any national coverage determination shall be subject to the following limitations:

(i) Such a determination shall not be reviewed by any administrative law judge.

(ii) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(iii) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services. In conducting such a review, the Departmental Appeals Board-

42 USC 1395gg: Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part E-Miscellaneous Provisions

Jump To:

§1395gg. Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals

(a) Payments to providers of services or other person regarded as payment to individuals

Any payment under this subchapter to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Incorrect payments on behalf of individuals; payment adjustment

Where-

(1) more than the correct amount is paid under this subchapter to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1395f(e) of this title to a provider of services or other person for items or services furnished an individual,

proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments-

(3) to which such individual is entitled under subchapter II of this chapter or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other individual is entitled under subchapter II of this chapter or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], as the case may be, with respect to the wages and self-employment income or the compensation constituting the basis of the benefits of such deceased individual under subchapter II of this chapter.

As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1395i(g) of this title, and section 1395t(f) of this title, shall certify (to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.]) the amount of the overpayment as to which the adjustment is to be made. For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter.

(c) Exception to subsection (b) payment adjustment

There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1395f(e) of this title) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by

decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of subchapter II or subchapter XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this subchapter) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this subchapter by reason of the provisions of paragraph (1) or (9) of section 1395y(a) of this title and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter.

(d) Liability of certifying or disbursing officer for failure to recoup

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person where the adjustment or recovery of such amount is waived under subsection (c) or where adjustment under subsection (b) is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

(e) Settlement of claims for benefits under this subchapter on behalf of deceased individuals

If an individual, who received services for which payment may be made to such individual under this subchapter, dies, and payment for such services was made (other than under this subchapter), and the individual died before any payment due him under this subchapter with respect to such services was completed, payment of the amount due (including the amount of any unnegotiated checks) shall be made-

(1) if the payment for such services was made (before or after such individual's death) by a person other than the deceased individual, to the person or persons determined by the Secretary under regulations to have paid for such services, or if the payment for such services was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any;

(2) if there is no person who meets the requirements of paragraph (1), to the person, if any, who is determined by the Secretary to be the surviving spouse of the deceased individual and who was either living in the same household with the deceased at the time of his death or was, for the month in which the deceased individual died, entitled to a monthly benefit on the basis of the same wages and self-employment income as was the deceased individual;

(3) if there is no person who meets the requirements of paragraph (1) or (2), or if the person who meets such requirements dies before the payment due him under this subchapter is completed, to the child or children, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(4) if there is no person who meets the requirements of paragraph (1), (2), or (3), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the parent or parents, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent);

(5) if there is no person who meets the requirements of paragraph (1), (2), (3), or (4), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the person, if any, determined by the Secretary to be the surviving spouse of the deceased individual;

(6) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), or (5), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the person or persons, if any, determined by the Secretary to be the child or children of the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(7) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), or (6), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the parent or parents, if any, of the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent); or

(8) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), (6), or (7), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the legal representatives of the estate of the deceased individual, if any.

(f) Settlement of claims for section 1395k benefits on behalf of deceased individuals

If an individual who received medical and other health services for which payment may be made under section 1395k(a)(1) of this title dies, and no assignment of the right to payment for such services was made by such individual before his death, and payment for such services has not been made-

(1) if the person or persons who furnished the services agree to the terms of assignment specified in section 1395u(b)(3)(B)(ii) of this title with respect to the services, payment for such services shall be made to such person or persons, and

(2) if the person or persons who furnished the services do not agree to the terms of assignment specified in section 1395u(b)(3)(B)(ii) of this title with respect to the services, payment for such services shall be made on the basis of an itemized bill to the person who has agreed to assume the legal obligation to make payment for such services and files a request for payment (with such accompanying evidence of such legal obligation as may be required in regulations),

but only in such amount and subject to such conditions as would be applicable if the individual who received the services had not died.

(g) Refund of premiums for deceased individuals

If an individual, who is enrolled under section 1395i–2(c) of this title or under section 1395p of this title, dies, and premiums with respect to such enrollment have been received with respect to such individual for any month after the month of his death, such premiums shall be refunded to the person or persons determined by the Secretary under regulations to have paid such premiums or if payment for such premiums was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any. If there is no person who meets the requirements of the preceding sentence such premiums shall be refunded to the person or persons in the priorities specified in paragraphs (2) through (7) of subsection (e).

(h) Appeals by providers of services or suppliers

Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services or supplier to appeal any determination of the Secretary under this subchapter relating to services rendered under this subchapter to an individual who subsequently dies if there is no other party available to appeal such determination.

(Aug. 14, 1935, ch. 531, title XVIII, §1870, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 331 ; amended Pub. L. 90–248, title I, §154(b), (c), Jan. 2, 1968, 81 Stat. 862 ; Pub. L. 92–603, title II, §§261(a), 266, 281(a), (b), Oct. 30, 1972, 86 Stat. 1448 , 1450, 1454, 1455; Pub. L. 93–445, title III, §309, Oct. 16, 1974, 88 Stat. 1358 ; Pub. L. 96–499, title IX, §954(a), Dec. 5, 1980, 94 Stat. 2647 ; Pub. L. 97–248, title I, §128(d)(1), Sept. 3, 1982, 96 Stat. 367 ; Pub. L. 100–203, title IV, §§4039(h)(7), 4096(a)(2), Dec, 22, 1987, 101 Stat. 1330–139 , as amended Pub. L. 100–360, title IV, §411(e)(3), July 1, 1988, 102 Stat. 776 ; Pub. L. 100–360, title IV, §411(j)(4)(B), July 1, 1988, 102 Stat. 791 ; Pub. L. 108–173, title IX, §939(a), Dec. 8, 2003, 117 Stat. 2416 ; Pub. L. 112–240, title VI, §638(a), Jan. 2, 2013, 126 Stat. 2357 .)

REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (b), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, §101, Oct. 16, 1974, 88 Stat. 1305 , which is classified generally to subchapter IV (§231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231t of Title 45, and Tables.

AMENDMENTS

2013-Subsecs. (b), (c). Pub. L. 112–240 substituted "fifth year" for "third year" and "five-year" for "three-year" in last sentence.

2003-Subsec. (h). Pub. L. 108–173 added subsec. (h).

1988-Pub. L. 100–360, §411(e)(3), added Pub. L. 100–203, §4039(h)(7), see 1987 Amendment note below.

Subsec. (f)(1), (2). Pub. L. 100–360, §411(j)(4)(B), substituted "of assignment specified in" for "specified in subclauses (I) and (II) of".

1987-Pub. L. 100–203, §4039(h)(7), as added by Pub. L. 100–360, §411(e)(3), amended section catchline generally.

Subsec. (f)(1), (2). Pub. L. 100–203, §4096(a)(2), substituted "to the terms specified in subclauses (I) and (II) of section 1395u(b)(3)(B)(ii) of this title with respect to the services" for "that the reasonable charge is the full charge for the services".

1982-Subsec. (c). Pub. L. 97–248 substituted "section 1395y(a)" for "section 1395y".

1980-Subsec. (f). Pub. L. 96–499 amended subsec. (f) generally, inserting provision for payments to providers of medical and other health services where the person or persons furnishing the services did not agree that the reasonable charge was the full charge for such services.

1974-Subsec. (b). Pub. L. 93–445 substituted "Railroad Retirement Act of 1974" for "Railroad Retirement Act of 1937", wherever appearing.

1972-Subsec. (b). Pub. L. 92–603, §281(a), required that provider of services or other person be without fault with respect to payment of excess over correct amount as prerequisite to adjustment or recovery of incorrect payments.

Subsec. (c). Pub. L. 92–603, §§261(a), 281(b), substituted "or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if" for "and where", inserted reference to subchapter XVIII of this chapter, and inserted provisions covering the adjustment or recovery of incorrect payments against individuals who are without fault.

Subsec. (g). Pub. L. 92–603, §266, added subsec. (g).

1968-Pub. L. 90–248, §154(b), provided for settlement of claims for benefits on behalf of deceased individuals in section catchline.

Subsecs. (e), (f). Pub. L. 90–248, §154(c), added subsecs. (e) and (f).

Effective Date of 2013 Amendment

Pub. L. 112–240, title VI, §638(b), Jan. 2, 2013, 126 Stat. 2357 , provided that: "The amendments made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Jan. 2, 2013]."

Effective Date of 2003 Amendment

Pub. L. 108–173, title IX, §939(b), Dec. 8, 2003, 117 Stat. 2416 , provided that: "The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003] and shall apply to items and services furnished on or after such date."

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date of 1987 Amendment

Amendment by section 4096(a)(2) of Pub. L. 100–203 applicable to services furnished on or after Jan. 1, 1988, see section 4096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

Effective Date of 1982 Amendment

Amendment by Pub. L. 97–248 effective Sept. 3, 1982, see section 128(e)(3) of Pub. L. 97–248, set out as a note under section 1395x of this title.

Effective Date of 1980 Amendment

Pub. L. 96–499, title IX, §954(b), Dec. 5, 1980, 94 Stat. 2647 , provided that: "The amendment made by this section [amending this section] shall apply only to claims filed on or after January 1, 1981."

Effective Date of 1974 Amendment

Amendment by Pub. L. 93–445 effective Jan. 1, 1975, see section 603 of Pub. L. 93–445, set out as a note under section 402 of this title.

Effective Date of 1972 Amendment

Pub. L. 92–603, title II, §261(b), Oct. 30, 1972, 86 Stat. 1448 , provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to waiver actions considered after the date of the enactment of this Act [Oct. 30, 1972]."

Pub. L. 92–603, title II, §281(g), Oct. 30, 1972, 86 Stat. 1456 , provided that: "The provisions of subsection (a)(1) [amending this section] shall apply with respect to notices of payment sent to individuals after the date of enactment of this Act [Oct. 30, 1972]. The provisions of subsections (a)(2), (b), (c), and (d) [amending this section and sections 1395u and 1395cc of this title] shall apply in the case of notices sent to individuals after 1968. The provisions of subsections (e) and (f) [amending sections 1395f and 1395n of this title] shall apply in the case of services furnished (or deemed to have been furnished) after 1970."

Waiver of Liability Limiting Recoupment in Certain Cases

Pub. L. 101–239, title VI, §6109, Dec. 19, 1989, 103 Stat. 2213 , provided that: "In the case where more than the correct amount may have been paid to a physician or individual under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to services furnished during the period beginning on July 1, 1985, and ending on March 31, 1986, as a result of a carrier's establishing statewide fees for certain procedure codes while the carrier was in the process of implementing the national common procedure coding system of the Health Care Financing Administration, the provisions of section 1870(c) of the Social Security Act [42 U.S.C. 1395gg(c)] shall apply, without the need for affirmative action by such a physician or individual, so as to prevent any recoupment, or other decrease in subsequent payments, to the physician or individual. The previous sentence shall apply to claims for items and services which were reopened by carriers on or after July 31, 1987."

42 USC 1395ddd: Medicare Integrity Program
Text contains those laws in effect on June 9, 2020

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 7-SOCIAL SECURITY
SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED
Part E-Miscellaneous Provisions

Jump To:

§1395ddd. Medicare Integrity Program

(a) Establishment of Program

There is hereby established the Medicare Integrity Program (in this section referred to as the "Program") under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities, or otherwise, to carry out the activities described in subsection (b).

(b) Activities described

The activities described in this subsection are as follows:

(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this subchapter (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this subchapter as of August 21, 1996).

(2) Audit of cost reports.

(3) Determinations as to whether payment should not be, or should not have been, made under this subchapter by reason of section 1395y(b) of this title, and recovery of payments that should not have been made.

(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1395m(a)(15) of this title which are subject to prior authorization under such section.

(6) The Medicare-Medicaid Data Match Program in accordance with subsection (g).

(c) Eligibility of entities

An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if-

(1) the entity has demonstrated capability to carry out such activities;

(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this subchapter and in other cases arising out of such activities;

(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(4) the entity agrees to provide the Secretary and the Inspector General of the Department of Health and Human Services with such performance statistics (including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity) as the Secretary or the Inspector General may request; and

(5) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b)(5), an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1395u of this title.

(d) Process for entering into contracts

The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

(2) Competitive procedures to be used-

(A) when entering into new contracts under this section;

(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1395h of this title or contracts under section 1395u of this title in effect on August 21, 1996.

(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

The Secretary may enter into such contracts without regard to final rules having been promulgated.

(e) Limitation on contractor liability

The Secretary shall by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1320c–6 of this title.

(f) Recovery of overpayments

(1) Use of repayment plans

(A) In general

If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this subchapter would constitute a hardship (as described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) Hardship

(i) In general

For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if-

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this subchapter to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this subchapter to the provider of services or supplier for the previous calendar year.

(ii) Rule of application

The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this subchapter during the previous year or was paid under this subchapter only during a portion of that year.

(iii) Treatment of previous overpayments

If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) Exceptions

Subparagraph (A) shall not apply if-

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this subchapter; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) Immediate collection if violation of repayment plan

If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) Relation to no fault provision

Nothing in this paragraph shall be construed as affecting the application of section 1395gg(c) of this title (relating to no adjustment in the cases of certain overpayments).

(2) Limitation on recoupment

(A) In general

In the case of a provider of services or supplier that is determined to have received an overpayment under this subchapter and that seeks a reconsideration by a qualified independent contractor on such determination under section 1395ff(b)(1) of this title, the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1395ff(b)(1) of this title (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) Collection with interest

Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) Medicare contractor defined

For purposes of this subsection, the term "medicare contractor" has the meaning given such term in section 1395zz(g) of this title.

(3) Limitation on use of extrapolation

A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that-

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

(4) Provision of supporting documentation

In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) Consent settlement reforms

(A) In general

The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) Opportunity to submit additional information before consent settlement offer

Before offering a provider of services or supplier a consent settlement, the Secretary shall-

(i) communicate to the provider of services or supplier-

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) Consent settlement offer

The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary-

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier-

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) Consent settlement defined

For purposes of this paragraph, the term "consent settlement" means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) Notice of over-utilization of codes

The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this subchapter (or provisions of subchapter XI insofar as they relate to such programs).

(7) Payment audits

(A) Written notice for post-payment audits

Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this subchapter, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) Explanation of findings for all audits

Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this subchapter, the contractor shall-

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this subchapter as well as consent settlement options (which are at the discretion of the Secretary);

(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) Exception

Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) Standard methodology for probe sampling

The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(g) Medicare-Medicaid Data Match Program

(1) Expansion of Program

(A) In general

The Secretary shall enter into contracts with eligible entities or otherwise for the purpose of ensuring that, beginning with 2006, the Medicare-Medicaid Data Match Program (commonly referred to as the "Medi-Medi Program") is conducted with respect to the program established under this subchapter and State Medicaid programs under subchapter XIX for the purpose of-

(i) identifying program vulnerabilities in the program established under this subchapter and the Medicaid program established under subchapter XIX through the use of computer algorithms to review claims data to look for payment anomalies (including billing or billing patterns identified with respect to provider, service, time, or patient that appear to be suspect or otherwise implausible);

(ii) working with States, the Attorney General, and the Inspector General of the Department of Health and Human Services to coordinate appropriate actions to investigate and recover amounts with respect to suspect claims to protect the Federal and State share of expenditures under the Medicaid program under subchapter XIX, as well as the program established under this subchapter;

(iii) increasing the effectiveness and efficiency of both such programs through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures; and

(iv) furthering the Secretary's design, development, installation, or enhancement of an automated data system architecture-

(I) to collect, integrate, and assess data for purposes of program integrity, program oversight, and administration, including the Medi-Medi Program; and

(II) that improves the coordination of requests for data from States.

(B) Reporting requirements

The Secretary shall make available in a timely manner any data and statistical information collected by the Medi-Medi Program to the Attorney General, the Director of the Federal Bureau of Investigation, the Inspector General of the Department of Health and Human Services, and the States (including a Medicaid fraud and abuse control unit described in section 1396b(q) of this title). Such information shall be disseminated no less frequently than quarterly.

(2) Limited waiver authority

The Secretary shall waive only such requirements of this section and of subchapters XI and XIX as are necessary to carry out paragraph (1).

(3) Incentives for States

The Secretary shall study and, as appropriate, may specify incentives for States to work with the Secretary for the purposes described in paragraph (1)(A)(ii). The application of the previous sentence may include use of the waiver authority described in paragraph (2).

(h) Use of recovery audit contractors

(1) In general

Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this subchapter with respect to all services for which payment is made under this subchapter. Under the contracts-

(A) payment shall be made to such a contractor only from amounts recovered;

(B) from such amounts recovered, payment-

(i) shall be made on a contingent basis for collecting overpayments; and

(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 405.940 - Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with § 405.906 (/regulations/42/405.906)(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with § 405.940 (/regulations/42/405.940) through § 405.958 (/regulations/42/405.958), regardless of the amount in controversy.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

All Titles (/regulations/) > Title 42 (/regulations/title42) > Chapter IV (/regulations/title42_chapterIV) > Part 405 (/regulations/title42_chapterIV_part405) > Subpart I - Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B) (/regulations/title42_chapterIV_part405_subpartI)

⊞ View all text of Subpart I [§ 405.900 - § 405.1140] (/regulations/expand/title42_chapterIV_part405_subpartI_subjgrp27_section405.960)

§ 405.960 - Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 (/regulations/42/405.940) through § 405.958 (/regulations/42/405.958), and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 (/regulations/42/405.962) through § 405.966 (/regulations/42/405.966), regardless of the amount in controversy.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

All Titles (/regulations/) > Title 42 (/regulations/title42) > Chapter IV (/regulations/title42_chapterIV) > Part 405 (/regulations/title42_chapterIV_part405) > Subpart I - Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B) (/regulations/title42_chapterIV_part405_subpartI)

⊞ View all text of Subpart I [§ 405.900 - § 405.1140] (/regulations/expand/title42_chapterIV_part405_subpartI_subjgrp30_section405.1000)

§ 405.1000 - Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 (/regulations/42/405.970) for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 (/regulations/42/405.1018) and § 405.1028 (/regulations/42/405.1028)), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010 (/regulations/42/405.1010), or join the hearing before an ALJ as a party under § 405.1012 (/regulations/42/405.1012).

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with § 405.1020 (/regulations/42/405.1020)(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020 (/regulations/42/405.1020)(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012 (/regulations/42/405.1012).

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

[82 FR 5109, Jan. 17, 2017]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

All Titles (/regulations/) > Title 42 (/regulations/title42) > Chapter IV (/regulations/title42_chapterIV) > Part 405 (/regulations/title42_chapterIV_part405) > Subpart I - Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B) (/regulations/title42_chapterIV_part405_subpartI)

⊞ View all text of Subpart I [§ 405.900 - § 405.1140] (/regulations/expand/title42_chapterIV_part405_subpartI_subjgrp30_section405.1016)

§ 405.1016 - Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in § 405.970 (/regulations/42/405.970), an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with § 405.970 (/regulations/42/405.970), unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events -

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation* - (1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f) (1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the

request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions -

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with § 405.1102 (/regulations/42/405.1102)(a), and the appeal will be escalated to the Council for a review in accordance with § 405.1108 (/regulations/42/405.1108); and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

[82 FR 5113, Jan. 17, 2017]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

⊞ View all text of Subpart I [§ 405.900 - § 405.1140] (/regulations/expand/title42_chapterIV_part405_subpartI_subjgrp32_section405.1100)

§ 405.1100 - Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 (/regulations/42/405.1016) and 405.1108 (/regulations/42/405.1108), the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

[82 FR 5122, Jan. 17, 2017]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 405.1108 - Council actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the Council review an ALJ's or attorney adjudicator's decision, the Council will review the ALJ's or attorney adjudicator's decision *de novo*. The party requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence in the administrative record. Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to an ALJ or attorney adjudicator for further proceedings.

(b) When a party requests that the Council review an ALJ's or attorney adjudicator's dismissal of a request for a hearing, the Council may deny review or vacate the dismissal and remand the case to the ALJ or attorney adjudicator for further proceedings.

(c) The Council will dismiss a request for review when the party requesting review does not have a right to a review by the Council, or will dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the OMHA level to the Council, the Council may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the Council determines are necessary to issue a decision.

(3) Remand the case to OMHA for further proceedings, including a hearing.

(4) Dismiss the request for Council review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5122, Jan. 17, 2017]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 409.42 - Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) *Confined to the home.* The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) *Under the care of a physician or allowed practitioner, as defined at § 484.2 (/regulations/42/484.2) of this chapter.* The beneficiary must be under the care of a physician or allowed practitioner, as defined at § 484.2 (/regulations/42/484.2) of this chapter who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.

(c) *In need of skilled services.* The beneficiary must need at least one of the following skilled services as certified by a physician or allowed practitioner, as defined at § 484.2 (/regulations/42/484.2) of this chapter in accordance with the certification and recertification requirements for home health services under § 424.22 (/regulations/42/424.22) of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32 (/regulations/42/409.32). (Also see § 409.33 (/regulations/42/409.33)(a) and (b) for a description of examples of skilled nursing and rehabilitation services.) These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

(2) Physical therapy services that meet the requirements of § 409.44 (/regulations/42/409.44)(c).

(3) Speech-language pathology services that meet the requirements of § 409.44 (/regulations/42/409.44)(c).

(4) Occupational therapy services in the current and subsequent certification periods (subsequent adjacent episodes) that meet the requirements of § 409.44 (/regulations/42/409.44)(c) initially qualify for home health coverage as a dependent service as defined in § 409.45 (/regulations/42/409.45)(d) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period. Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44 (/regulations/42/409.44)(c) are considered to be qualifying services.

(d) *Under a plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 409.43 (/regulations/42/409.43).

(e) *By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by, a participating HHA.

[59 FR 65494, Dec. 20, 1994; 60 FR 39122, Aug. 1, 1995, as amended at 74 FR 58133, Nov. 10, 2009; 76 FR 68606, Nov. 4, 2011; 85 FR 27619, May 8, 2020]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 411.406 - Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15 (/regulations/42/411.15)(g) or that are not reasonable and necessary under § 411.15 (/regulations/42/411.15)(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) *Notice from the QIO, intermediary or carrier.* The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending phyician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that -

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

⊞ View all text of Subpart A [§ 421.1 - § 421.5] (/regulations/expand/title42_chapterIV_part421_subpartA_section421.1)

§ 421.1 - Basis, applicability, and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act:

Section 1124 - Requirements for disclosure of certain information.

Sections 1816 and 1842 - Provisions relating to the administration of Parts A and B.

Section 1893 - Requirements for protecting the integrity of the Medicare program.

(b) *Applicability.* The provisions of this part apply to agreements with Part A (Hospital Insurance) fiscal intermediaries that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, contracts with Part B (Supplementary Medical Insurance) carriers that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, and contracts with Medicare integrity program contractors that perform program integrity functions.

(c) *Scope.* The scope of this part -

(1) Specifies that CMS may perform certain functions directly or by contract.

(2) Specifies criteria and standards CMS uses in evaluating the performance of fiscal intermediaries' successor entities and in assigning or reassigning a provider or providers to particular fiscal intermediaries.

(3) Provides the opportunity for a hearing for fiscal intermediaries and carriers affected by certain adverse actions.

(4) Provides adversely affected fiscal intermediaries an opportunity for judicial

review of certain hearing decisions.

(5) Sets forth requirements related to contracts with Medicare integrity program contractors.

[72 FR 48886, Aug. 24, 2007]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.3 - Definitions.

As used in this part -

Intermediary means an entity that has a contract with CMS (under statutory provisions in effect prior to October 1, 2005) to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the prospective payment system for hospitals) and to perform other related functions. For purposes of applying the performance criteria in § 421.120 (/regulations/42/421.120) and the performance standards in § 421.122 (/regulations/42/421.122) and any adverse action resulting from that application, the term "intermediary" also means a Blue Cross plan that has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[71 FR 68228, Nov. 24, 2006]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.5 - General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.200 - Carrier functions.

A contract between CMS and a carrier specifies the functions to be performed by the carrier. The contract may include any or all of the following functions:

(a) Any or all of the program integrity functions described in § 421.304 (/regulations/42/421.304) provided the following conditions are met:

(1) The carrier is continuing those functions under a contract entered into under section 1842 of the Act that was in effect on August 21, 1996.

(2) The functions do not duplicate work being performed under a Medicare integrity program contract, except that the function related to developing and maintaining a list of DME may be performed under both a carrier contract and a Medicare integrity program contract.

(b) Receiving, disbursing, and accounting for funds in making payments for services furnished to eligible individuals within the jurisdiction of the carrier.

(c) Determining the amount of payment for services furnished to an eligible individual.

(d) Undertaking to adjust incorrect payments and recover overpayments when it is determined that an overpayment was made.

(e) Furnishing to CMS timely information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(f) Maintaining records and making available to CMS the records necessary for verification of payments and for other related purposes.

(g) Establishing and maintaining procedures under which an individual enrolled under Part D is granted an opportunity for a redetermination.

(h) Upon inquiry, assisting individuals with matters pertaining to a carrier contract.

(i) Serving as a channel of communication to and from CMS of information, instructions, and other material as necessary for the effective and efficient performance of a carrier contract.

(j) Undertaking other functions as mutually agreed to by CMS and the carrier.

[72 FR 48886, Aug. 24, 2007]

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.300 - Basis, applicability, and scope.

(a) *Basis.* This subpart implements section 1893 of the Act, which requires CMS to protect the integrity of the Medicare program by entering into contracts with eligible entities to carry out Medicare integrity program functions. The provisions of this subpart are based on section 1893 of the Act (and, where applicable, section 1874A of the Act) and the acquisition regulations set forth at 48 CFR chapters (/regulations/48/chapters) 1 and 3.

(b) *Applicability.* This subpart applies to entities that seek to compete or receive award of a contract under section 1893 of the Act, including entities that perform functions under this subpart emanating from the processing of claims for individuals entitled to benefits as qualified railroad retirement beneficiaries.

(c) *Scope.* The scope of this subpart follows:

(1) Defines the types of entities eligible to become Medicare integrity program contractors.

(2) Identifies the program integrity functions a Medicare integrity program contractor performs.

(3) Describes procedures for awarding and renewing contracts.

(4) Establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest.

(5) Prescribes responsibilities.

(6) Sets forth limitations on contractor liability.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.302 - Eligibility requirements for Medicare integrity program contractors.

(a) CMS may enter into a contract with an entity to perform the functions described in § 421.304 (/regulations/42/421.304) if the entity meets the following conditions:

(1) Demonstrates the ability to perform the Medicare integrity program contractor functions described in § 421.304 (/regulations/42/421.304). For purposes of developing and periodically updating a list of DME under § 421.304 (/regulations/42/421.304)(e), an entity is deemed to be eligible to enter into a contract under the Medicare integrity program to perform the function if the entity is a carrier with a contract in effect under section 1842 of the Act.

(2) Agrees to cooperate with the OIG, the DOJ, and other law enforcement agencies, as appropriate, including making referrals, in the investigation and deterrence of potential fraud and abuse of the Medicare program.

(3) Complies with conflict of interest provisions in 48 CFR chapters (/regulations/48/chapters) 1 and 3, and is not excluded under the conflict of interest provision at § 421.310 (/regulations/42/421.310).

(4) Maintains an appropriate written code of conduct and compliance policies that include, but are not limited to, an enforced policy on employee conflicts of interest.

(5) Meets other requirements that CMS establishes.

(b) A MAC as described in section 1874A of the Act may perform any or all of the functions described in § 421.304 (/regulations/42/421.304), except that the functions may not duplicate work being performed under a Medicare integrity program contract.

(c) If a MAC performs any or all functions described in § 421.304 (/regulations/42/421.304), CMS may require the MAC to comply with any or all of the requirements of paragraph (a) of this section as a condition of its contract.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.304 - Medicare integrity program contractor functions.

The contract between CMS and a Medicare integrity program contractor specifies the functions the contractor performs. The contract may include any or all of the following functions:

(a) Conducting medical reviews, utilization reviews, and reviews of potential fraud related to the activities of providers of services and other individuals and entities (including entities contracting with CMS under parts 417 and 422 of this chapter) furnishing services for which Medicare payment may be made either directly or indirectly.

(b) Auditing, settling and determining cost report payments for providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 of this chapter), as necessary to help ensure proper Medicare payment.

(c) Determining whether a payment is authorized under title XVIII, as specified in section 1862(b) of the Act, and recovering mistaken and conditional payments under section 1862(b) of the Act.

(d) Educating providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues.

(e) Developing, and periodically updating, a list of items of DME that are frequently subject to unnecessary utilization throughout the contractor's entire service area or a portion of the area, in accordance with section 1834(a)(15)(A) of the Act.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.306 - Awarding of a contract.

(a) CMS awards and administers Medicare integrity program contracts in accordance with acquisition regulations set forth at 48 CFR chapters (/regulations/48/chapters) 1 and 3, this subpart, all other applicable laws, and all applicable regulations. These requirements for awarding Medicare integrity program contracts are used as follows:

(1) When entering into new contracts.

(2) When entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 1816(l) or section 1842(c) of the Act, respectively.

(3) At any other time CMS considers appropriate.

(b) CMS may award an entity a Medicare integrity program contract by transfer if all of the following conditions apply:

(1) Through approval of a novation agreement in accordance with the requirements of the Federal Acquisition Regulation (FAR), CMS recognizes the entity as the successor in interest to a fiscal intermediary agreement or carrier contract under which the fiscal intermediary or carrier was performing activities described in section 1893(b) of the Act on August 21, 1996.

(2) The fiscal intermediary or carrier continued to perform Medicare integrity program activities until transferring the resources to the entity.

(c) An entity is eligible to be awarded a Medicare integrity program contract only if it meets the eligibility requirements specified in § 421.302 (/regulations/42/421.302); 48 CFR chapters (/regulations/48/chapters) 1 and 3; and other applicable laws and regulations.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.308 - Renewal of a contract.

(a) *General.* (1) CMS specifies an initial contract term in the Medicare integrity program contract.

(2) Contracts under this subpart may contain renewal clauses.

(3) CMS may, but is not required to, renew the Medicare integrity program contract, without regard to any provision of law requiring competition, as it determines to be appropriate, by giving the contractor notice, within timeframes specified in the contract, of its intent to do so.

(b) *Conditions for renewal of contract.* CMS may renew a Medicare integrity program contract if all of the following conditions are met:

(1) The Medicare integrity program contractor continues to meet the requirements established in this subpart.

(2) The Medicare integrity program contractor meets or exceeds the performance requirements established in its current contract.

(3) It is in the best interest of the government.

(c) *Nonrenewal of a contract.* If CMS does not renew a contract, the contract ends in accordance with its terms.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.310 - Conflict of interest requirements.

Offerors for MIP contracts and MIP contractors are subject to the following:

(a) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance specified under 48 CFR subpart (/regulations/48/subpart) 9.5.

(b) The standards and requirements as are contained in each individual contract awarded to perform section 1893 of the Act functions.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.312 - Conflict of interest resolution.

(a) *Review Board.* CMS may establish and convene a Conflicts of Interest Review Board to assist the contracting officer in resolving organizational conflicts of interest.

(b) *Resolution* - (1) *Pre-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict precludes award of a contract to the offeror.

(iii) It is in the best interest of the government to award a contract to the offeror (in accordance with 48 CFR subpart (/regulations/48/subpart) 9.503) even though a conflict of interest exists.

(2) *Post-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict requires that CMS modify an existing contract.

(iii) The conflict requires that CMS terminate or not renew an existing contract.

(iv) It is in the best interest of the government to continue the contract even though a conflict of interest exists.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.316 - Limitation on Medicare integrity program contractor liability.

(a) A MIP contractor, a person or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a MIP contractor is not in violation of any criminal law or civilly liable under any law of the United States or of any State (or political subdivision thereof) by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart, provided due care was exercised in that performance and the contractor has a contract with CMS under this subpart.

(b) CMS pays a contractor, a person or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if the following conditions are met:

(1) The suit, action, or proceeding was brought against the contractor, such person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS under this subpart.

(2) The funds are available.

(3) The expenses are otherwise allowable under the terms of the contract.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

All Titles (/regulations/) > Title 42 (/regulations/title42) > Chapter IV (/regulations/title42_chapterIV0) > Part 421 (/regulations/title42_chapterIV_part421) > Subpart E - Medicare Administrative Contractors (MACs) (/regulations/title42_chapterIV_part421_subpartE)

⊞ View all text of Subpart E [§ 421.400 - § 421.404] (/regulations/expand/title42_chapterIV_part421_subpartE_section421.400)

§ 421.400 - Statutory basis and scope.

(a) *Statutory basis.* This subpart implements section 1874A of the Act, which provides for the transition of the claims processing functions and operations for both Medicare Part A and Part B intermediaries and carriers to Medicare Administrative Contractors (MACs). The transition will occur between October 1, 2005, and October 1, 2011. MACs will be fully operational in distinct, nonoverlapping geographic jurisdictions by October 1, 2011.

(b) *Scope.* This subpart specifies the requirements under which providers and suppliers will be assigned to MACs.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.401 - Definitions.

For purposes of this subpart -

Appropriate MAC means a MAC that has a contract under section 1874A of the Act to perform a particular Medicare administrative function in relation to:

(1) A particular individual entitled to benefits under Part A or enrolled under Part B, or both;

(2) A specific provider of services or supplier; or

(3) A class of providers of services or suppliers.

Medicare Administrative Contractor (MAC) means an agency, organization, or other person with a contract under section 1874A of the Act.

U.S. CODE OF FEDERAL REGULATIONS

Regulations most recently checked for updates: Jun 10, 2020

§ 421.404 - Assignment of providers and suppliers to MACs.

(a) *Definitions.* As used in this section -

Chain provider means a group of two or more providers under common ownership or control.

Common control exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.

Common ownership exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.

Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) means the types of services specified in § 421.210 (/regulations/42/421.210)(b).

Eligible provider means a hospital, skilled nursing facility, or critical access hospital that meets the definition of a provider under § 400.202 (/regulations/42/400.202) of this chapter.

Home office means the entity that provides centralized management and administrative services to the individual providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services.

Ineligible provider means a provider under § 400.202 (/regulations/42/400.202) of this

chapter that is not an eligible provider.

Medicare benefit category means a category of covered benefits under Part A or Part B of the Medicare program (for example, inpatient hospital services, post-hospital extended care services, and physicians'services).

Provider has the same meaning as specified under § 400.202 (/regulations/42/400.202) of this chapter.

Qualified chain provider means a chain provider comprised of -

(1) 10 or more eligible providers collectively totaling 500 or more certified beds; or

(2) 5 or more eligible providers collectively totaling 300 or more certified beds, with eligible providers in 3 or more contiguous States.

Supplier has the same meaning as specified in § 400.202 (/regulations/42/400.202) of this chapter.

(b) *Assignment of providers to MACs.* (1) Providers enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the provider's covered services for the geographic locale in which the provider is physically located.

(2) Qualified chain providers may request and receive an exception from the requirement of paragraph (b)(1) of this section from CMS. Upon CMS'approval, a qualified chain provider may enroll with and bill on behalf of the eligible providers under its common ownership or common control to the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the eligible providers'covered services for the geographic locale in which the qualified chain provider's home office is physically located.

(3) As MAC contractors become available, qualified chain providers, granted approval by CMS to enroll with and bill a single intermediary on behalf of their eligible member providers prior to October 1, 2005, will be assigned at an appropriate time to the MAC contracted by CMS to administer claims for the applicable Medicare benefit category for the geographic locale in which the chain provider's home office is physically located. The qualified chain provider will not need to request an exception to the requirement of paragraph (b)(1) of this section in order for this assignment to take effect.

(4) CMS may grant an exception to the requirement of paragraph (b)(1) of this section to eligible providers that are not under the common ownership or common control of a qualified chain provider, as well as ineligible providers, only if CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

(c) *Assignment of suppliers to MACs.* (1) Suppliers, including physicians and other practitioners, but excluding suppliers of DMEPOS, enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the supplier's covered services for the geographic locale in which the supplier furnished such services.

(2) Suppliers of DMEPOS receive Medicare payment and other Medicare services from the MAC assigned to administer claims for DMEPOS for the regional area in which the beneficiary receiving the DMEPOS resides. The terms of §§ 421.210 (/regulations/42/421.210) and 421.212 (/regulations/42/421.212) continue to apply to suppliers of DMEPOS.

(3) CMS may allow a group of ESRD suppliers under common ownership and common control to enroll with the MAC contracted by CMS to administer ESRD claims for the geographic locale in which the group's home office is located only if -

(i) The group of ESRD suppliers requests such privileges; and

(ii) CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.