No. 20-1114

IN THE

Supreme Court of the United States

THE AMERICAN HOSPITAL ASSOCIATION, et al.,

Petitioners,

v.

XAVIER BECERRA, in his official capacity as the Secretary of Health and Human Services, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED: February 10, 2021
CERTIORARI GRANTED: July 2, 2021

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Docket No. 18-2084

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
Plaintiffs

v.

ALEX M. AZAR, II, ET AL.,
Defendants

RELEVANT DOCKET ENTRIES

Date Filed	Docket Number	Docket Text
9/5/2018	1	COMPLAINT against ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Filing fee $ 400 receipt number 0090-5672969) filed by FLETCHER HOSPITAL, INC., EASTERN MAINE HEALTHCARE SYSTEMS, AMERICAN HOSPITAL ASSOCIATION, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, HENRY FORD HEALTH SYSTEM. (Attachments:

Date Filed	Docket Number	Docket Text
		# 1 Summons Alex M. Azar II, # 2 Summons U.S. Department of Health and Human Services, # 3 Civil Cover Sheet) (Schultz, William) (Entered: 09/05/2018)
9/5/2018	2	MOTION for Preliminary Injunction and Permanent Injunction by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM (Attachments: # 1 Memorandum in Support, # 2 Exhibit Index, # 3 Exhibit A, # 4 Exhibit B-1, # 5 Exhibit B-2, # 6 Exhibit C, # 7 Exhibit D, # 8 Exhibit E, # 9 Exhibit F, # 10 Exhibit G, # 11 Exhibit H, # 12 Exhibit I, # 13 Exhibit J, # 14 Exhibit K, # 15 Exhibit L, # 16 Exhibit M, # 17 Exhibit N, # 18 Exhibit O,

Date Filed	Docket Number	Docket Text
		# 19 Exhibit P, # 20 Exhibit Q, # 21 Exhibit R, # 22 Exhibit S, # 23 Exhibit T, # 24 Exhibit U, # 25 Exhibit V, # 26 Exhibit W, # 27 Exhibit X, # 28 Text of Proposed Order) (Schultz, William). Added MOTION for Permanent Injunction on 9/12/2018 (znmw). (Entered: 09/05/2018)
		* * *
9/14/2018	14	MOTION to Dismiss by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Exhibit, # 2 Exhibit, # 3 Text of Proposed Order) (Sandberg, Justin) (Entered: 09/14/2018)
9/14/2018	15	RESPONSE re MOTION for Preliminary Injunction and Permanent Injunction MOTION for Permanent Injunction filed by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Exhibit, # 2 Exhibit) (Sandberg,

Date Filed	Docket Number	Docket Text
		Justin) (Entered: 09/14/2018)
9/26/2018	16	RESPONSE re MOTION to Dismiss and Reply in Support of Motion for Preliminary and Permanent Injunction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM. (Attachments: # 1 Supplemented Exhibit L, # 2 Supplemented Exhibit N, # 3 Supplemented Exhibit P, # 4 Supplemented Exhibit R, # 5 Exhibit Y) (Marcus, Ezra) (Entered: 09/26/2018)
9/26/2018	18	REPLY to opposition to motion re MOTION for Preliminary Injunction and Permanent Injunction MOTION for Permanent Injunction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN

Date Filed	Docket Number	Docket Text
		HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM. (See Docket Entry 16 to view document) (tth) (Entered: 10/01/2018)
		* * *
10/9/2018	19	NOTICE *of Administrative Decision* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM (Attachments: # 1 EAJR Ruling) (Marcus, Ezra) (Entered: 10/09/2018)
10/10/2018	20	REPLY to opposition to motion re 14 MOTION to Dismiss filed by ALEX M. AZAR II, DEPARTMENT

Date Filed	Docket Number	Docket Text
		OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 10/10/2018)
		* * *
12/3/2018	23	NOTICE *of Administrative Decisions* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Supplemented Exhibit I, # 2 Supplemented Exhibit J) (Marcus, Ezra) (Entered: 12/03/2018)
12/27/2018	24	ORDER denying Defendants' Motion to Dismiss; granting Plaintiffs' Motion for a Permanent Injunction; and denying as moot Plaintiffs' Motion for a Preliminary Injunction. See document for details. Signed by Judge Rudolph Contreras on December

Date Filed	Docket Number	Docket Text
		27, 2018. (lcrc3) (Entered: 12/27/2018)
12/27/2018	25	MEMORANDUM OPINION denying Defendants' Motion to Dismiss; granting Plaintiffs' Motion for a Permanent Injunction; and denying as moot Plaintiffs' Motion for a Preliminary Injunction. See document for details. Signed by Judge Rudolph Contreras on December 27, 2018. (lcrc3) (Entered: 12/27/2018)
		* * *
1/9/2019	28	NOTICE OF SUPPLEMENTAL AUTHORITY by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 USCA Order) (Marcus, Ezra) (Entered: 01/09/2019)

Date Filed	Docket Number	Docket Text
		* * *
1/31/2019	31	MEMORANDUM by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Declaration) (Sandberg, Justin) (Entered: 01/31/2019)
1/31/2019	32	MEMORANDUM by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Attachments: # 1 Exhibit A) (Marcus, Ezra) (Entered: 01/31/2019)
		* * *
2/7/2019	33	Unopposed MOTION for Leave to File Amicus Curiae Brief by FEDERATION OF AMERICAN HOSPITALS (Attachments: # 1 Exhibit A - Amicus Brief, # 2 Text of

Date Filed	Docket Number	Docket Text
		Proposed Order) (Carroll, Kelly) (Entered: 02/07/2019)
2/7/2019	34	Unopposed MOTION for Leave to File Supplemental Complaint by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order) (Marcus, Ezra) (Entered: 02/07/2019)
2/8/2019		MINUTE ORDER granting Unopposed Motion for Leave to File Amicus Curiae Brief. It is hereby ORDERED that the Amicus Curiae brief attached to the motion (ECF No. 33-1) is DEEMED FILED. SO ORDERED. Signed by Judge Rudolph Contreras on February 8, 2019.

Date Filed	Docket Number	Docket Text
		(lcrc3) (Entered: 02/08/2019)
2/8/2019		MINUTE ORDER granting Plaintiffs' Unopposed Motion for Leave to File Supplemental Complaint. It is hereby ORDERED that Exhibit C to Plaintiffs' motion (ECF No. 34-3) is deemed filed and served as the operative pleading in this case. SO ORDERED. Signed by Judge Rudolph Contreras on February 8, 2019. (lcrc3) (Entered: 02/08/2019)
2/8/2019	38	AMICUS BRIEF by FEDERATION OF AMERICAN HOSPITALS. (znmw) (Entered: 02/20/2019)
2/8/2019	39	SUPPLEMENTAL COMPLAINT against ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES filed by FLETCHER HOSPITAL, INC., AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL

Date Filed	Docket Number	Docket Text
		COLLEGES, AMERICAN HOSPITAL ASSOCIATION, NORTHERN LIGHT HEALTH, HENRY FORD HEALTH SYSTEM.(znmw) (Entered: 02/20/2019)
2/11/2019	35	MOTION for Permanent Injunction by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Text of Proposed Order)(Schultz, William) (Entered: 02/11/2019)
2/14/2019	36	RESPONSE Regarding Appropriate Remedy filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 02/14/2019)

Date Filed	Docket Number	Docket Text
2/14/2019	37	SUPPLEMENTAL MEMORANDUM to re Order on Motion for Preliminary Injunction,, Order on Motion for Permanent Injunction,, Order on Motion to Dismiss, filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Dotzel, Margaret) (Entered: 02/14/2019)
2/21/2019	40	MOTION for Leave to File Amicus Curiae Brief of the Federation of American Hospitals in Response to Defendants Opposition Brief on Remedy by FEDERATION OF AMERICAN HOSPITALS. (Attachments: # 1 Exhibit A - FAH Response Brief, # 2 Text of Proposed Order) (Carroll, Kelly) (Entered: 02/21/2019)

Date Filed	Docket Number	Docket Text
2/22/2019	41	NOTICE OF APPEAL TO DC CIRCUIT COURT by UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II. Fee Status: No Fee Paid. Parties have been notified. (Sandberg, Justin) (Entered: 02/22/2019)
2/22/2019	42	Partial MOTION to Dismiss , Partial MOTION to Dismiss for Lack of Jurisdiction by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Text of Proposed Order) (Sandberg, Justin) (Entered: 02/22/2019)
2/22/2019	43	Memorandum in opposition to re MOTION for Permanent Injunction filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 02/22/2019)

Date Filed	Docket Number	Docket Text
		* * *
2/26/2019	45	REPLY to opposition to motion re MOTION for Permanent Injunction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 02/26/2019)
2/26/2019	46	Memorandum in opposition to re Partial MOTION to Dismiss Partial MOTION to Dismiss for Lack of Jurisdiction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 02/26/2019)

Date Filed	Docket Number	Docket Text
		* * *
3/15/2019	47	NOTICE Of Motion to Stay Appeal by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Attachments: # 1 Exhibit Motion to Hold Appeal in Abeyance) (Schultz, William) (Entered: 03/15/2019)
3/27/2019	48	ORDER of USCA as to Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; USCA Case Number 19-5048. (zrdj) (Entered: 04/01/2019)
5/06/2019	49	ORDER granting in part and denying in part motion for permanent injunction; granting motion for

Date Filed	Docket Number	Docket Text
		leave to file; denying motion to dismiss: See document for details. Signed by Judge Rudolph Contreras on 5/6/19. (lcrc1) (Entered: 05/06/2019)
5/06/2019	50	MEMORANDUM OPINION granting in part and denying in part motion for permanent injunction; granting motion for leave to file; denying motion to dismiss: See document for details. Signed by Judge Rudolph Contreras on 5/6/19. (lcrc1) (Entered: 05/06/2019)
5/10/2019	51	MOTION for a Firm Date by which Defendants Must Propose a Remedy , MOTION to Expedite Response Deadline by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Attachments: # 1 Text of

Date Filed	Docket Number	Docket Text
		Proposed Order, # 2 Text of Proposed Order) (Marcus, Ezra) (Entered: 05/10/2019)
		* * *
5/31/2019	53	RESPONSE re MOTION for a Firm Date by which Defendants Must Propose a Remedy MOTION to Expedite Response Deadline filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 05/31/2019)
6/3/2019	54	MOTION for Entry of Final Judgment, MOTION for Reconsideration of May 6, 2019 Order, MOTION to Expedite Briefing by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Text of Proposed Order) (Sandberg, Justin) (Entered: 06/03/2019)

Date Filed	Docket Number	Docket Text
6/4/2019		MINUTE ORDER: Upon consideration of Defendants' Motion for Reconsideration, Entry of Final Judgment, and Expedited Briefing, it is hereby ORDERED that the motion for expedited consideration is GRANTED. It is FURTHER ORDERED that Plaintiffs shall file their response brief to Defendants' motion by no later than June 11, 2019. SO ORDERED. Signed by Judge Rudolph Contreras on June 4, 2019. (lcrc3) (Entered: 06/04/2019)
6/4/2019	55	REPLY to opposition to motion re MOTION for a Firm Date by which Defendants Must Propose a Remedy MOTION to Expedite Response Deadline filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT

Date Filed	Docket Number	Docket Text
		HEALTH. (Marcus, Ezra) (Entered: 06/04/2019)
6/7/2019	56	RESPONSE re MOTION for Entry of Final Judgment MOTION for Reconsideration of May 6, 2019 Order MOTION to Expedite Briefing filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 06/07/2019)
6/10/2019	57	REPLY to opposition to motion re MOTION for Entry of Final Judgment MOTION for Reconsideration of May 6, 2019 Order MOTION to Expedite Briefing filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 06/10/2019)

Date Filed	Docket Number	Docket Text
		* * *
7/10/2019		Minute Entry for proceedings held before Judge Rudolph Contreras: Status Conference held on 7/10/2019. Parties inform the court of the status of this action. (Court Reporter: Patricia Kaneshiro Miller.) (tj) (Entered: 07/10/2019)
7/10/2019	58	ORDER granting Defendants' Motion for Entry of Final Judgment and denying as moot Plaintiffs' Motion for a Firm Date. See document for details. Signed by Judge Rudolph Contreras on July 10, 2019. (lcrc3) Modified on 7/10/2019 (lcrc3). Modified on 7/10/2019 (lcrc3). (Entered: 07/10/2019)
7/10/2019	59	MEMORANDUM OPINION granting Defendants' Motion for Entry of Final Judgment and denying as moot Plaintiffs' Motion for a Firm Date. See document for details. Signed by Judge Rudolph Contreras on July 10, 2019.

Date Filed	Docket Number	Docket Text
		(lcrc3) (Entered: 07/10/2019)
7/11/2019	60	NOTICE OF APPEAL TO DC CIRCUIT COURT by UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II. Fee Status: No Fee Paid. Parties have been notified. (Sandberg, Justin) (Entered: 07/11/2019)
		* * *
7/15/2019		USCA Case Number 19-5198 for Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (zrdj) (Entered: 07/16/2019)
10/26/2020		MANDATE of USCA as to Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR, II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Notice of Appeal to DC Circuit Court

Date Filed	Docket Number	Docket Text
		filed by ALEX M. AZAR, II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ; USCA Case Number 19-5048 Consolidated with 19-5198. (Attachments: # 1 USCA Judgment) (zrdj) (Entered: 10/27/2020)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Docket No. 19-5198

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
Plaintiffs-Appellees

v.

ALEX AZAR, II, ET AL.,
Defendants-Appellants

RELEVANT DOCKET ENTRIES

DATE	PROCEEDINGS
	* * *
7/15/2019	NOTICE OF APPEAL [1797187] seeking review of a decision by the U.S. District Court in 1:18-cv-02084-RC filed by Mr. Alex Michael Azar, II and HHS. Appeal assigned USCA Case Number: 19-5198. [19-5198] [Entered: 07/15/2019 02:59 PM]
	* * *
7/23/2019	STATEMENT OF ISSUES [1798573] filed by Mr. Alex Michael Azar, II and HHS [Service Date: 07/23/2019] [19-5198] (Myron, Laura) [Entered: 07/23/2019 02:52 PM]
	* * *
7/24/2019	MOTION [1798888] to expedite case, to establish briefing schedule filed by

DATE	PROCEEDINGS
	America's Essential Hospitals, American Hospital Association, Association of American Medical Colleges, Fletcher Hospital, Inc., Henry Ford Health System and Northern Light Health (Service Date: 07/24/2019 by CM/ECF NDA) Length Certification: 2,410 words. [19-5198] (Schultz, William) [Entered: 07/24/2019 05:09 PM]
	* * *
9/3/2019	APPELLANT BRIEF [1804789] filed by Mr. Alex Michael Azar, II and HHS in 19-5198, 19-5048 [Service Date: 09/03/2019] Length of Brief: 8,774 words. [19-5198, 19-5048] (Myron, Laura) [Entered: 09/03/2019 08:05 PM]
9/3/2019	*JOINT* APPENDIX [1804790] filed by Mr. Alex Michael Azar, II and HHS in 19-5198, 19-5048. [Volumes: 1] [Service Date: 09/03/2019] [19-5198, 19-5048] (Myron, Laura) [Entered: 09/03/2019 08:22 PM]
9/10/2019	AMICUS FOR APPELLANT BRIEF [1805870] filed by Federation of American Hospitals in 19-5198, 19-5048 [Service Date: 09/10/2019] Length of Brief: 3,568 Words. [19-5198, 19-5048]--[Edited 09/11/2019 by JAD--MODIFIED PARTY FILER] (London, Andrew) [Entered: 09/10/2019 01:54 PM]

DATE	PROCEEDINGS
	* * *
9/11/2019	*CORRECTED* AMICUS FOR APPELLANT BRIEF [1806058] filed by Federation of American Hospitals in 19-5198, 19-5048 [Service Date: 09/11/2019] Length of Brief: 3,568 Words. [19-5198, 19-5048) (London, Andrew) [Entered: 09/11/2019 02:39 PM]
9/24/2019	APPELLEE BRIEF [1807851] filed by America's Essential Hospitals, American Hospital Association, Association of American Medical Colleges, Fletcher Hospital, Inc., Henry Ford Health System and Northern Light Health in 19-5198, 19-5048 [Service Date: 09/24/2019] Length of Brief: 12,411 words. [19-5198, 19-5048] (Schultz, William) [Entered: 09/24/2019 02:47 PM]
	* * *
10/15/2019	*CORRECTED* APPELLANT REPLY BRIEF [1810886] filed by HHS and Mr. Alex Michael Azar, II in 19-5048, 19-5198 [Service Date: 10/15/2019] Length of Brief: 4,800 words. [19-5048, 19-5198] (Myron, Laura) [Entered: 10/15/2019 04:38 PM]
	* * *

DATE	PROCEEDINGS
11/8/2019	ORAL ARGUMENT HELD before Judges Srinivasan, Millett and Pillard. [19-5048, 19-5198] [Entered: 11/13/2019 10:36 AM]
11/12/2019	LETTER [1815284] pursuant to FRAP 28j advising of additional authorities filed by Mr. Alex Michael Azar II and HHS in 19-5048, 19-5198 [Service Date: 11/12/2019] [19-5048, 19-5198] (Klein, Alisa) [Entered: 11/12/2019 02:16 PM]
11/14/2019	LETTER [1815803] pursuant to FRAP 28j advising of additional authorities filed by America's Essential Hospitals, American Hospital Association, Association of American Medical Colleges, Fletcher Hospital, Inc., Henry Ford Health System and Northern Light Health in 19-5048, 19-5198 [Service Date: 11/14/2019] [19-5048, 19-5198] (Schultz, William) [Entered: 11/14/2019 01:09 PM]
11/15/2020	TRANSCRIPT [1816110] of oral argument [19-5048, 19-5198] [Entered: 11/15/2019 03:58 PM]
7/31/2020	PER CURIAM JUDGMENT [1854491] filed that the judgment of the District Court appealed from in these causes be reversed, for the reasons in the accompanying opinion. Before Judges: Srinivasan, Millett and Pillard. [19-5048, 19-5198] [Entered: 07/31/2020 10:47 AM]

DATE	PROCEEDINGS
7/31/2020	OPINION [1854504] filed (Pages: 30) for the Court by Judge Srinivasan, OPINION DISSENTING IN PART (Pages: 12) by Judge Pillard. [19-5048, 19-5198] [Entered: 07/31/2020 10:54 AM]
7/31/2020	CLERK'S ORDER [1854508] filed withholding issuance of the mandate. [19-5048, 19-5198] [Entered: 07/31/2020 10:56 AM]
	* * *
9/14/2020	PETITION [1861298] for rehearing en banc filed by Appellees America's Essential Hospitals, American Hospital Association, Association of American Medical Colleges, Fletcher Hospital, Inc., Henry Ford Health System and Northern Light Health in 19-5048, 19-5198 [Service Date: 09/14/2020 by CM/ECF NDA] Length Certification: 3896. [19-5048, 19-5198] (Verrilli, Donald) [Entered: 09/14/2020 02:07 PM]
9/14/2020	NOTICE [1861303] to substitute party filed by Fletcher Hospital, Inc. in 19-5048, 19-5198 [Service Date: 09/14/2020] [19-5048, 19-5198] (Verrilli, Donald) [Entered: 09/14/2020 02:14 PM]
10/16/2020	PER CURIAM ORDER, En Banc, [1866841] filed denying appellees' petition for rehearing en banc [1861298-

DATE	PROCEEDINGS
	2] Before Judges: Srinivasan, Henderson, Rogers, Tatel, Garland, Millett, Pillard, Wilkins, Katsas, Rao* and Walker. [19-5048, 19-5198] (Circuit Judge Rao did not participate in this matter) [Entered: 10/16/2020 04:45 PM]
10/26/2020	MANDATE ISSUED to Clerk, U.S. District Court. [19-5048, 19-5198] [Entered: 10/26/2020 03:03 PM]

[82 Fed. Reg. 52,356 (Nov. 13, 2017)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, and 419

[CMS–1678–FC]

RIN 0938-AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2018, unless otherwise noted.

* * *

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association

AMA American Medical Association

AMI Acute myocardial infarction

APC Ambulatory Payment Classification

API Application programming interface

APU Annual payment update

ASC Ambulatory surgical center

ASCQR Ambulatory Surgical Center Quality Reporting

ASP Average sales price

AUC Appropriate use criteria

AWP Average wholesale price

BBA Balanced Budget Act of 1997, Public Law 105–33

BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113

BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554

BLS Bureau of Labor Statistics

CAH Critical access hospital

CAHPS Consumer Assessment of Healthcare Providers and Systems

CAP Competitive Acquisition Program

C–APC Comprehensive Ambulatory Payment Classification

CASPER Certification and Survey Provider Enhanced Reporting

CAUTI Catheter-associated urinary tract infection

CBSA Core-Based Statistical Area

CCM Chronic care management

CCN CMS Certification Number

CCR Cost-to-charge ratio

CDC Centers for Disease Control and Prevention

CED Coverage with Evidence Development

CERT Comprehensive Error Rate Testing

CFR Code of Federal Regulations

CI Comment indicator

CLABSI Central Line [Catheter] Associated Blood Stream Infection

CLFS Clinical Laboratory Fee Schedule

CMHC Community mental health center

CMS Centers for Medicare & Medicaid Services

CoP Condition of participation

CPI–U Consumer Price Index for All Urban Consumers

CPT Current Procedural Terminology (copyrighted by the American Medical Association)

CR Change request

CRC Colorectal cancer

CSAC Consensus Standards Approval Committee

CT Computed tomography

CV Coefficient of variation

CY Calendar year

DFO Designated Federal Official

DME Durable medical equipment

DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies

DOS Date of service

DRA Deficit Reduction Act of 2005, Public Law 109–171

DSH Disproportionate share hospital

EACH Essential access community hospital

EAM Extended assessment and management

ECD Expanded criteria donor

EBRT External beam radiotherapy

ECG Electrocardiogram

ED Emergency department

EDTC Emergency department transfer communication

EHR Electronic health record

E/M Evaluation and management

ESRD End-stage renal disease

ESRDQIP End-Stage Renal Disease Quality Improvement Program

FACA Federal Advisory Committee Act, Public Law 92–463

FDA Food and Drug Administration

FFS [Medicare] Fee-for-service

FY Fiscal year

GAO Government Accountability Office

GI Gastrointestinal

GME Graduate medical education

HAI Healthcare-associated infection

HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems

HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152

HCP Health care personnel

HCPCS Healthcare Common Procedure Coding System

HCRIS Healthcare Cost Report Information System

HCUP Healthcare Cost and Utilization Project

HEU Highly enriched uranium

HHQRP Home Health Quality Reporting Program

HHS Department of Health and Human Services

HIE Health information exchange

HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191

HOP Hospital Outpatient Payment [Panel]

HOPD Hospital outpatient department

HOPQDRP Hospital Outpatient Quality Data Reporting Program

HPMS Health Plan Management System

IBD Inflammatory bowel disease

ICC Interclass correlation coefficient

ICD Implantable cardioverter defibrillator

ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification

ICD–10 International Classification of Diseases, Tenth Revision

ICH In-center hemodialysis

ICR Information collection requirement

IDTF Independent diagnostic testing facility

IGI IHS Global, Inc.

IHS Indian Health Service

I/OCE Integrated Outpatient Code Editor

IOL Intraocular lens

IORT Intraoperative radiation treatment

IPFQR Inpatient Psychiatric Facility Quality Reporting

IPPS [Hospital] Inpatient Prospective Payment System

IQR [Hospital] Inpatient Quality Reporting

IRF Inpatient rehabilitation facility

IRFQRP Inpatient Rehabilitation Facility Quality Reporting Program

IT Information technology

LCD Local coverage determination

LDR Low dose rate

LTCH Long-term care hospital

LTCHQR Long-Term Care Hospital Quality Reporting

MAC Medicare Administrative Contractor

MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10

MAP Measure Application Partnership

MDH Medicare-dependent, small rural hospital

MedPAC Medicare Payment Advisory Commission

MEG Magnetoencephalography

MFP Multifactor productivity

MGCRB Medicare Geographic Classification Review Board

MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432

MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275

MLR Medical loss ratio

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173

MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309

MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173

MPFS Medicare Physician Fee Schedule

MR Medical review

MRA Magnetic resonance angiography

MRgFUS Magnetic Resonance Image Guided Focused Ultrasound

MRI Magnetic resonance imaging

MRSA Methicillin-Resistant Staphylococcus Aureus

MS–DRG Medicare severity diagnosis-related group

MSIS Medicaid Statistical Information System

MUC Measure under consideration

NCCI National Correct Coding Initiative

NEMA National Electrical Manufacturers Association

NHSN National Healthcare Safety Network

NOTA National Organ and Transplantation Act

NOS Not otherwise specified

NPI National Provider Identifier

NQF National Quality Forum

NQS National Quality Strategy

NTIOL New technology intraocular lens

NUBC National Uniform Billing Committee

OACT [CMS] Office of the Actuary

OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509

O/E Observed to expected event

OIG [HHS] Office of the Inspector General

OMB Office of Management and Budget

ONC Office of the National Coordinator for Health Information Technology

OPD [Hospital] Outpatient Department

OPPS [Hospital] Outpatient Prospective Payment System

OPSF Outpatient Provider-Specific File

OQR [Hospital] Outpatient Quality Reporting

OT Occupational therapy

PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93

PCHQR PPS-Exempt Cancer Hospital Quality Reporting

PCR Payment-to-cost ratio

PDC Per day cost

PDE Prescription Drug Event

PE Practice expense

PHP Partial hospitalization program

PHSA Public Health Service Act, Public Law 96–88

PN Pneumonia

POS Place of service

PPI Producer Price Index

PPS Prospective payment system

PQRI Physician Quality Reporting Initiative

PQRS Physician Quality Reporting System

QDC Quality data code

QIO Quality Improvement Organization

RFA Regulatory Flexibility Act

RHQDAPU Reporting Hospital Quality Data for Annual Payment Update

RTI Research Triangle Institute, International

RVU Relative value unit

SAD Self-administered drug

SAMS Secure Access Management Services

SCH Sole community hospital

SCOD Specified covered outpatient drugs

SES Socioeconomic status

SI Status indicator

SIA Systems Improvement Agreement

SIR Standardized infection ratio

SNF Skilled nursing facility

SRS Stereotactic radiosurgery

SRTR Scientific Registry of Transplant Recipients

SSA Social Security Administration

SSI Surgical site infection

TEP Technical Expert Panel

TOPs Transitional Outpatient Payments

VBP Value-based purchasing

WAC Wholesale acquisition cost

Table of Contents

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2018. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this

final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

* * *

• *340B Drug Pricing:* We are changing our current Medicare Part B drug payment methodology for 340B hospitals that we believe will better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. These changes will lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program. For CY 2018, we are exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. In addition, in this final rule with comment period, we are establishing two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program.

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D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for

hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

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In the CY 2018 OPPS/ASC proposed rule (82 FR 33712), we estimated a 1.4 percent adjustment to nondrug OPPS payment rates as a result of the proposed payment adjustment to separately payable nonpass-through drugs purchased under the 340B Program. As part of that proposed policy, we noted that our adjustment in the final rule could potentially change as a result of changes such as updated data, modifications to the estimate methodology, and other factors. Applying the final payment policy for drugs purchased under the 340B Program, as described in section V.B.7. of this final rule with comment period, results in an estimated reduction of approximately $1.6 billion in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after

applying this alternative payment methodology for drugs purchased under the 340B Program, we applied an offset of approximately $1.6 billion into the OPPS conversion factor, which results in a final adjustment of 1.0319 to the OPPS conversion factor.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2018 OPPS is 1.35 percent (which is 2.7 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.6 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2018, we are using a conversion factor of $78.636 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 1.35 percent for CY 2018, the required wage index budget neutrality adjustment of approximately 0.9997, the cancer hospital payment adjustment of 1.0008, the adjustment for drugs purchased under the 340B Program of 1.0319, and the adjustment of 0.2 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a conversion factor for CY 2018 of $78.636.

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2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these

items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

• A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.

• A drug or biological for which a temporary HCPCS code has not been assigned.

• During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and the subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment by equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and

adjusted by the Secretary as necessary. We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[17]

It has been our policy since CY 2006 to apply the same treatment to all separately payment drugs and biologicals, which includes SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by the statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals,

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[17] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.

including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CY 2014, CY 2015, CY 2016, and CY 2017 (81 FR 79673).

b. CY 2018 Payment Policy

In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue our payment policy that has been in effect from CY 2013 to present and pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section

1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals.

We note that we proposed, as specified below, to pay for separately payable, nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to the full discussion of this proposal in section V.B.7. of the proposed rule and this final rule with comment period.

Comment: Numerous commenters supported CMS' proposal to continue to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). The ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2018. In addition, we are finalizing our proposal that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payment of these separately paid drugs and biologicals. We refer readers to section V.B.7. of the final rule with comment period for the final payment policy for drugs acquired with a 340B discount.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the Internet on the CMS Web site), which illustrate the final CY 2018 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2017, or WAC, AWP, or mean unit cost from CY 2016 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not the same as the actual January 2018 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2018 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2017 (July 1, 2017 through September 30, 2017) will be used to set the payment rates that are released for the quarter beginning in January 2018 near the end of December 2017. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2017 are based on mean unit cost in the available CY 2016 claims data. If ASP information becomes available for payment for the quarter beginning in January 2018, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2017 ASP data) that do not have ASP information available for the quarter beginning

in January 2018. As stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33630), these drugs and biologicals will then be paid based on mean unit cost data derived from CY 2016 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2018 payment purposes and are only illustrative of the CY 2018 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

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7. Alternative Payment Methodology for Drugs Purchased Under the 340B Program

a. Background

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.[18]

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[18] The House report that accompanied the authorizing legislation for the 340B Program stated: "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more

The 340B statute defines which health care providers are eligible to participate in the program ("covered entities"). In addition to Federal health care grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. However, under Public Law 111–148, section 7101 expanded eligibility to critical access hospitals (CAHs), children's hospitals with a DSH adjustment greater than 11.75 percent, sole community hospitals (SCHs) with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers (RRCs) with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. In accordance with section 340B(a)(4)(L)(i) of the Public Health Service Act, all participating hospital types must also meet other criteria.

HRSA calculates the ceiling price for each covered outpatient drug. The ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug.[19] The ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug. However,

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comprehensive services." (H.R. Rept. No. 102–384(II), at 12 (1992)).

[19] 42 U.S.C. 256b(a)(1–2). Occasionally, a drug's URA is equal to its AMP, resulting in a 340B ceiling price of $0. In these instances, HRSA has advised manufacturers to charge covered entities $0.01 per unit.

covered entities also have the option to participate in HRSA's Prime Vendor Program (PVP), under which the prime vendor can negotiate even deeper discounts (known as "subceiling prices") on some covered outpatient drugs. By the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price.[20]

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33632 and 33633), several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost.[21] [22] [23] Links

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[20] Department of Health and Human Services. 2017. Fiscal Year 2018 Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. Available at: *https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf*.

[21] Office of Inspector General. "Part B Payment for 340B Purchased Drugs. OEI–12–14–00030". November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf*.

[22] Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Available at: *http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0*.

[23] Government Accountability Office. "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO–15–442". June 2015. Available at: *https://www.gao.gov/assets/680/670676.pdf*.

to the full reports referenced in this section can be found in the cited footnotes.

In its May 2015 Report to Congress, MedPAC analyzed Medicare hospital outpatient claims (excluding CAHs) along with information from HRSA on which hospitals participate in the 340B Program. MedPAC included data on all separately payable drugs under the OPPS except for vaccines and orphan drugs provided by freestanding cancer hospitals, RRCs, and SCHs. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPPS, MedPAC generally used the formula for calculating the 340B ceiling price: (AMP)—unit rebate amount (URA) × drug package size. The URA is determined by law and depends upon whether a drug is classified as single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides this URA information to States as a courtesy. However, drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs. More information on the URA calculation and the Medicaid Drug Rebate Program may be found on the Web site at: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html*.

Because MedPAC did not have access to AMP data, it used each drug's ASP as a proxy for AMP. MedPAC noted that ASP is typically slightly lower than AMP. The AMP is defined under section 1927(k)(1) of the Act as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. Manufacturers participating in Medicaid are required to report AMP data quarterly to

the Secretary, and these prices are confidential. As described under section 1847A of the Act, the ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge and 340B discounts.

In addition, MedPAC noted that, due to data limitations, its estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. Further details on the methodology used to calculate the average minimum discount for separately payable drugs can be found in Appendix A of MedPAC's May 2015 Report to Congress. In this report, MedPAC estimated that, on average, hospitals in the 340B Program "receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS]."

In its March 2016 Report to Congress (page 79), MedPAC noted that another report, which MedPAC attributed to the Office of the Inspector General (OIG), recently estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs. According to the U.S. Government Accountability Office (GAO) report, the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, participation in the PVP often results in a covered entity paying a subceiling price on some covered outpatient drugs

(estimated to be approximately 10 percent below the ceiling price) (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification). Participation in the PVP is voluntary and free.

As noted in the CY 2018 OPPS/ASC proposed rule, with respect to chemotherapy drugs and drug administration services, MedPAC examined Medicare Part B spending for 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that "Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period" (MedPAC May 2015 Report to Congress, page 14). This is just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs.

Further, GAO found that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals." According to the GAO report, this indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status (GAO Report 15–442, page 20).

Under the OPPS, all hospitals (other than CAHs, which are paid based on 101 percent of reasonable costs as required by section 1834(g) of the Act) are currently paid the same rate for separately payable drugs (ASP+6 percent), regardless of whether the hospital purchased the drug at a discount through the 340B Program. Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug" (OIG November 2015, Report OEI–12–14–00030, page 9).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68655), we requested comments regarding the drug costs of hospitals that participate in the 340B Program and whether we should consider an alternative drug payment methodology for participating 340B hospitals. As noted above, in the time since that comment solicitation, access to the 340B Program was expanded under section 7101 of Public Law 111–148, which amended section 340B(a)(4) of the Public Health Service Act to expand the types of covered entities eligible to participate in the 340B Program. It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013.[24] In

[24] U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342.

addition, the number of hospitals participating in the program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 (MedPAC May 2015 Report to Congress). In its November 2015 report entitled "Part B Payments for 340B-Purchased Drugs," the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013 (OEI–12–14–00030, page 8). Given the growth in the number of providers participating in the 340B Program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we stated in the CY 2018 OPPS/ASC proposed rule that we believe it is timely to reexamine the appropriateness of continuing to apply the current OPPS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B Program at significantly discounted rates.

MedPAC and OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. In its March 2016 Report to Congress, MedPAC recommended a legislative proposal related to payment for Part B drugs furnished by 340B hospitals under which Medicare would reduce payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the ASP and direct the program savings from reducing Part B drug payment rates to the Medicare funded uncompensated care pool.[25] In its

[25] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at: *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0*.

November 2015 report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the program savings realized by hospitals and other covered entities that participate in the 340B Program (OEI–12–14–00030, pages 11–12). These options included: (1) Paying ASP with no additional add-on percentage; (2) paying ASP minus 14.4 percent; and (3) making payment based on the 340B ceiling price plus 6 percent of ASP for each 340B purchased drug (OEI–12–14–00030, page 11). Analysis in several of these reports notes limitations in estimating 340B-purchased drugs' acquisition costs; the inability to identify which drugs were purchased through the 340B Program within Medicare claims data was one of those limitations.

b. OPPS Payment Rate for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33633 through 33634), we proposed changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare

beneficiaries and other patients. Medicare expenditures on Part B drugs have been rising and are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending due to a number of underlying factors such as new higher price drugs and price increases for existing drugs.[26] [27] While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs. We believe that any payment changes we adopt should be limited to separately payable drugs under the OPPS, with some additional exclusions. As a point of further clarity, CAHs are not included in this 340B policy change because they are paid under section 1834(g) of the Act. As stated in the CY 2018 OPPS/ASC proposed rule, these exclusions are for: (1) Drugs on pass-through payment status, which are required to be paid based on the ASP methodology, and (2) vaccines, which are excluded from the 340B Program. In addition, we solicited public comments on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

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[26] Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf*.

[27] Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf*.

Data limitations inhibit our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the proposed rule that we intended to provide further details about this modifier in this CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program.

A summary of public comments received and our responses pertaining to the modifier are included later in this section. As described in detail later in this section, we are implementing the modifier such that it is required for drugs that were acquired under the 340B Program instead of requiring its use on drugs that were *not* acquired under the 340B Program. In addition, we are establishing an informational

modifier for use by certain providers who will be excepted from the 340B payment reduction.

Further, we note that the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug. We recognize that each separately payable OPPS drug will have a different ceiling price (or subceiling price when applicable). Accordingly, we stated in the proposed rule that we believe using an average discounted price was appropriate for our proposal. Therefore, for CY 2018, we proposed to apply an average discounted price of 22.5 percent of the ASP for nonpass-through separately payable drugs purchased under the 340B Program, as estimated by MedPAC (MedPAC's May 2015 Report to Congress, page 7).

In the near-term, we believe that the estimated average minimum discount MedPAC calculated—22.5 percent of the ASP—adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate and noted that the analysis is spelled out in detail and can be replicated by interested parties. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent of the ASP. As GAO mentioned, discounts under the 340B Program range from 20 to 50 percent of the ASP (GAO–11–836, page 2). We believe that such reduced payment would meet the requirements under section 1833(t)(14)(A)(iii)(II)

of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary. We do not have hospital acquisition cost data for 340B drugs and, therefore, proposed to continue to pay for these drugs under our authority at section 1833(t)(14)(A)(iii)(II) of the Act at ASP, and then to adjust that amount by applying a reduction of 22.5 percent, which, as explained throughout this section, is the adjustment we believe is necessary for drugs acquired under the 340B Program.

Specifically, in the CY 2018 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. However, we proposed to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program, we proposed to adjust the rate to ASP minus 22.5 percent, which we believe better represents the average acquisition cost for these drugs and biologicals.

As indicated earlier, because ceiling prices are confidential, we are unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug. We believe that the MedPAC analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the

OPPS receive. In addition, we believe that using an average discount to set payment rates for OPPS separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs, and (2) protecting the confidential nature of discounts applied to a specific drug. Moreover, we do not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug under the 340B Program is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis because vaccines are not covered under the 340B Program, but it did not exclude drugs with pass-through payment status. Further, because data used to calculate ceiling prices are not publicly available, MedPAC instead estimated "the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]" (MedPAC May 2015 Report to Congress, page 6). Accordingly, it is likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis. In the proposed rule, we encouraged the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted earlier, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program, and in many cases, the average discount may be higher for some covered outpatient drugs due to hospital participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and

that drugs with pass-through payment status were included rather than excluded from the MedPAC analysis. We believe that a payment rate of ASP+6 percent does not sufficiently recognize the significantly lower acquisition costs of such drugs incurred by a 340B-participating hospital. Accordingly, as noted earlier, we proposed to reduce payment for separately payable drugs, excluding drugs on pass-through payment status and vaccines, that were acquired under the 340B Program by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier mentioned in the proposed rule and discussed further in this final rule with comment period. (As detailed later in this section, we are instead requiring hospitals to append the applicable modifier on the claim line with any drugs that were acquired under the 340B Program.)

Finally, as detailed in the impact analysis section (section XIX.A.5.a.2) of the proposed rule, we also proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program. In that section, we also solicited public comments on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we requested public comments on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those

patients who are uninsured. In addition, we requested public comments on whether savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal was included in section XIX.A.5.a.2. of the proposed rule. A summary of the public comments received on the impact estimate, along with our responses to those comments and our estimate of this provision for this final rule with comment period, are included in section XVIII.A.5. of this final rule with comment period.

c. Summaries of Public Comments Received and Our Responses

(1) Overall Comments

Comment: Several commenters, including organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, and preserve patient access to community-based care.

One of these commenters stated that the proposals would reduce drug costs for seniors by an estimated $180 million a year; help to stop hospital "abuses" of the 340B program; and help reverse the "perverse incentives" that have driven the closure and consolidation of the nation's community cancer care system.

Another commenter, representing a large network of community-based oncology practices, noted that since 2008, 609 community cancer practices have been acquired or become affiliated with hospitals, with 75 percent of those community cancer practices acquired by 340B-participating hospitals. The commenter stated that the consolidation in oncology care has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more costly hospital outpatient setting.

One commenter, an organization representing community oncology practices, cited several issues that the proposal would help address, including that only a small minority of 340B participating hospitals are using the program to benefit patients in need; cancer patients in need are being denied care at 340B participating hospitals or placed on wait lists; and hospitals are making extreme profits on expensive cancer drugs and are consolidating the nation's cancer care system, reducing patient choice and access and shifting care away from the private, physician-owned community oncology clinics into the more expensive 340B hospital setting, which is increasing costs for Medicare and its beneficiaries. In addition, this commenter stated that the increasing scope and magnitude of required 340B discounts are increasing drug prices to record-breaking levels as manufacturers factor these discounts into pricing decisions. The commenter also cited a report that it recently released that suggests, and provides anecdotal evidence supporting, that some 340B hospitals offered little

charity care and turned away some patients in need because those patients were uninsured.[28]

With respect to the magnitude of the proposed payment reduction of ASP minus 22.5 percent, one commenter noted that although the proposed decrease in payment may seem "severe," ASP minus 22.5 percent is the minimum discount that hospitals in the 340B Program receive. The commenter further noted that, with 340B discounts on brand drugs approaching, and even exceeding, 50 percent, there is still substantial savings—on the order of 50 percent drug margins—for hospitals to use to provide direct and indirect patient benefits. The commenter also noted that this proposal would result in cost-sharing savings to Medicare beneficiaries, for whom drug cost is an important component of overall outpatient cancer care costs.

Some commenters urged HHS, specifically CMS and HRSA, to work with Congress to reform the 340B Program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the "340B patient," which the commenter noted would require a legislative change.

Response: We thank the commenters for their support. As mentioned in the proposed rule, we share the commenters' concern that current Medicare payments for drugs acquired under the 340B Program are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We

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[28] Community Oncology Alliance. Report: "How Abuse of the 340B Program is Hurting Patients" September 2017. Available at: *https://www.communityoncology.org/wp-content/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf*.

continue to believe that our proposal would better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs. Importantly, we continue to believe that Medicare beneficiaries should be able to share in the savings on drugs acquired through the 340B Program at a significant discount. We also appreciate the comments supporting the proposed payment amount for drugs acquired under the 340B Program of ASP minus 22.5 percent, which we believe, like several commenters, is an amount that allows hospitals to retain a profit on these drugs for use in the care of low-income and uninsured patients. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments.

As previously stated, CMS does not administer the 340B Program. Accordingly, feedback related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: Several commenters expressed concern with the rising cost of drugs and the impact on beneficiaries and taxpayers. These commenters offered varied opinions on whether the proposal would achieve CMS' goal of lowering drug prices and reducing beneficiary out-of-pocket costs. Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients. Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs,

especially oncology drugs, CMS should not finalize the proposal.

One commenter, an individual who supported the proposal, stated that although the majority of patients with Medicare Part B coverage have supplemental coverage to pay their coinsurance, significant numbers do not have this additional protection. The commenter noted that, for a drug that is paid at $10,000 per month, the price reduction would save a beneficiary approximately $500 a month, which may be the difference between getting treatment and foregoing treatment due to financial reasons.

Another commenter, a large organization with many members who are Medicare beneficiaries, stated that the proposal would provide a measure of price relief to the 16 percent of Medicare beneficiaries without supplemental coverage. The commenter also expressed concern that the proposal would have serious health implications for beneficiaries in safety-net hospitals. The commenter urged HHS to develop proposals that will lower underlying drug prices, but did not provide any specific examples of such proposals. Another commenter stated that the cost of drugs is becoming unsustainable and applying the proposed policy is a decent "baby step" in controlling a situation that is "grossly" unfair to American taxpayers, especially when the development of new drugs is frequently funded to a large extent by taxpayers through Federal grants.

In addition, one commenter, a large organization representing its physician and medical student members, commented that it shares the Administration's interest in addressing the rising costs of drugs and biologicals. The commenter appreciated that the proposal would address a

longstanding concern: That the current payment policy for Part B drugs creates strong incentives to move Medicare beneficiary care from lower cost sites of care (such as physician offices) to higher cost sites of care (such as hospital outpatient departments). The commenter noted that many smaller physician practices have had to refer cancer and other patients who need chemotherapy and other expensive drugs to the hospital outpatient setting because the ASP+6 percent payment does not always cover a physician's acquisition cost, thereby undermining continuity of care and creating burdens for frail and medically compromised patients.

This commenter also stated that, given the 340B Program's focus on low-income patients, it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs. Further, the commenter noted that it is essential that "a bright line policy does not inadvertently deleteriously impact patient access in all sites of care." Finally, the commenter stated that, while the proposed policy alters the relative disparity between payments for some hospital outpatient departments and physician practices, it still does not address the persistent challenges physician practices face in obtaining payment that covers acquisition costs.

Response: We thank the commenters' for their feedback and share their concern about the high cost of drugs and their effect on Medicare beneficiaries. As discussed in detail later in this section, we are finalizing a change to the payment rate for certain

Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. We look forward to working with Congress to provide HHS additional 340B programmatic flexibility, which could include tools to provide additional considerations for safety net hospitals, which play a critical role in serving our most vulnerable populations.

As a general matter, we note that, even though many beneficiaries have supplemental coverage, beneficiaries often pay a premium for such supplemental coverage and those plans make coinsurance payments for the beneficiary. Thus, to the extent Medicare would be lessening the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans to decrease or otherwise reflect these lower costs in the future, thereby lowering the amount that beneficiaries pay for supplemental plan coverage. Further, for those Medicare beneficiaries who do not have supplemental coverage at all or who have a supplemental plan that does not cover all of a beneficiary's cost-sharing obligation, the proposed policy would directly lower out-of-pocket spending for 340B-acquired drugs for those beneficiaries.

In addition, we note that in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a "facility fee" solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 Drug Administration services and believe that these steps, taken together, may help encourage site-neutral care

in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

As previously stated, we believe that ASP minus 22.5 percent is a lower bound estimate of the average discount given to hospitals participating in the 340B Program. Accordingly, we disagree that this proposal represents a "bright-line" policy that would hinder safety-net hospitals' ability to treat patients.

While the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority, and we are committed to finding ways for Medicare payment policy not to incentivize use of overpriced drugs. With respect to Medicare Part B drug payment under the OPPS, we believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments. Further, to the extent that studies have found that 340B participating hospitals tend to use more high cost drugs, we believe that this proposal helps address the incentive for hospitals to utilize these drugs in this manner solely for financial reasons.

The expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs are outside the authority conferred by section 1833(t) of the Act (and, thus, are outside the scope of the proposed rule), and we see no reason to withdraw the proposal solely on account of these issues not being addressed by the proposal. Likewise, we note that the

public comments on Medicare Part B drug payment in the physician office setting are also outside the scope of the proposed rule, and, therefore, are not addressed in this final rule with comment period.

Comment: Several commenters, including organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals, were generally opposed to the proposed changes and urged CMS to withdraw the proposal from consideration. As detailed further below, these commenters believed that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs, and contended that such change would effectively eviscerate the 340B Program. The commenters further noted that Medicare payment cuts of this magnitude would greatly "undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program."

These commenters urged that, rather than "punitively targeting" 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS instead redirect its efforts to halt the "unchecked, unsustainable increases" in the price of drugs.

Response: We do not believe that our proposed policy "punitively" targets safety-net hospitals. The current OPPS payment rate of ASP+6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout this section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive. We

also have noted that 340B participation does not appear to be well-aligned with the provision of uncompensated care, as some commenters suggested. As stated earlier in this section, while the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority.

(2) Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. These comments are summarized into the broad categories below. For the reasons stated below, we disagree with these comments and believe that our proposal is within our statutory authority to promulgate.

• *Secretary's Authority To Calculate and Adjust 340B-Acquired Drug Payment Rates*

Comment: Commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act does not authorize CMS to "calculate and adjust" the payment rate in a manner that would "eviscerate" the 340B Program as it applies to 340B hospitals. Some commenters asserted that the plain and ordinary meaning of the terms "calculate" and "adjust" express a limited and circumscribed authority to set the payment rate. The commenters noted that the Oxford Dictionaries define "calculate" as "determine (the amount or number of something) mathematically;" likewise, to "adjust" is to "alter or move (something) slightly in order to achieve the desired fit, appearance, or result." Consequently, the commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act restricts the agency to mathematically determining "an appropriate, slight alteration." Further, they posited that the law does not

convey the power to adopt what they referred to as a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would result in a reduction in payment to 340B hospitals of at least $900 million, according to the agency's own estimates, or $1.65 billion, according to the commenter's estimates.

Another commenter stated that the Secretary's limited adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act does not "extend so far as to gut" what it referred to as an "explicit statutory directive". For example, the commenter referred the agency to *Pettibone Corp.* v. *United States*, 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute "must not be confused with a power to rewrite").

Some commenters, including an organization representing over 1,300 providers enrolled in the 340B Program, argued that the proposal would take away almost the entire 340B discount for many 340B drugs, especially brand name drugs (which they asserted were many of the drugs affected by the proposal). These commenters asserted that the Secretary does not have the authority to calculate and adjust 340B-acquired drug rates in this manner and noted that the standard 340B ceiling price for a brand name drug is AMP minus 23.1 percent, although the price can be lower if the drug's best price is lower or if the manufacturer increases the price of the drug more quickly than the rate of inflation. In addition, the commenters asserted that if a brand name drug's 340B ceiling price was based on the standard formula, the proposal would strip the hospital of nearly all its 340B savings because "AMP has been found to be close to ASP." Thus, the commenters asserted, the proposed

payment rate of ASP minus 22.5 percent is nearly identical to AMP minus 23.1 percent, leaving the hospital with "virtually no 340B savings."

Some commenters stated that the proposal mistakenly assumes that 340B hospitals purchase most 340B drugs at subceiling prices negotiated by the PVP. These commenters noted that some hospitals estimate that less than 10 percent of the drugs affected by the proposal are available at a subceiling price.

In addition, some commenters contended that subclause (I) of section 1833(t)(14)((A)(iii) establishes that the payment rate for subsequent years be set to the average acquisition cost of the drug taking into account hospital acquisition costs survey data collected through surveys meeting precise statutory requirements, and that such subclause does not provide adjustment authority for the agency. They stated that subclause (II) of section 1833(t)(14)((A)(iii) of the Act directs CMS, where acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the commenters stated that the statute reflects Congress's intent to limit CMS' authority to set payment rates and, consequently, is consistent with adjustment authority under subclause (II)—to convey only limited authority for any agency to adjust the payment rate. The commenters referred to *Roberts* v. *Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (Statutory provisions ". . . cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme") to support their conclusions, although the commenters did not elaborate on the particular relevance of this case.

Finally, some commenters raised concern over the Secretary's use of the May 2015 MedPAC estimate as support for the 340B payment proposal. These commenters stated that the Secretary did not conduct his own independent analysis to support the payment proposal nor did he provide justification for use of MedPAC's analysis. One commenter stated that the Secretary cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal and that relying on a MedPAC analysis does not suffice for this "important fiduciary, and legal, requirement."

Response: We believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. We disagree that this Medicare payment policy would effectively eviscerate the 340B Program and note that this proposal solely applies to applicable drug payments under the Medicare program; it does not change a hospital's eligibility for the 340B program. Further, under our proposal, we anticipate that the Medicare payment rate would continue to exceed the discounted 340B price the hospital received under the 340B program.

As previously stated, MedPAC's estimate of ASP minus 22.5 percent represents a lower bound estimate of the average minimum discount and the actual discount is likely much higher—up to 50 percent higher, according to some estimates, for certain drugs. In some cases, beneficiary coinsurance alone exceeds

the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). We did not receive public comments suggesting an alternative minimum discount off the ASP that would better reflect the hospital acquisition costs for 340B-acquired drugs. We believe this is notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs. The fact that hospitals did not submit comments suggesting an alternative minimum discount that would be a better, more accurate reflection of the discount at issue is instructive for two reasons. One, it gives us confidence that our suggested payment of ASP minus 22.5 percent is, in fact, the low bound of the estimate and keeps Medicare payment within the range where hospitals will not be underpaid for their acquisition costs of such drugs. Two, it gives us confidence that the affected hospital community does not believe there is some other number, such as ASP minus 24 percent or ASP minus 17 percent, that would be a better, more accurate measure of what Medicare Part B should pay for drugs acquired at a discount through the 340B Program. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate because MedPAC's estimate is based on all drugs separately paid under the OPPS except for vaccines, which are not eligible for 340B prices. Furthermore, the analysis is publicly available and can be replicated by interested parties.

With respect to the comments about the PVP, as previously stated, by the end of FY 2015, the PVP had nearly 7,600 products available to participating

entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price. Participation in the PVP is voluntary and free, and we are aware of no reason that an eligible entity would not participate.

Furthermore, we disagree that the Secretary's authority under section 1834(t)(14)(A)(iii)(II) of the Act to calculate and adjust drugs rates as necessary is limited to what some might consider minor changes and find no evidence in the statute to support that position. As previously stated, we believe that ASP minus 22.5 percent represents the average minimum discount that hospitals paid under the OPPS received for drugs acquired under the 340B Program and reiterate that, in many instances, the discount is much higher. Thus, we are using this authority to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs.

• *Authority To Vary Payment by Hospital Group*

Comment: Some commenters asserted that only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment "by hospital group." These commenters suggested that, by including "by hospital group" in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II). They further commented that the subparagraph (II) methodology must apply to "the drug," and CMS may not vary payment for the same drug based upon the type of hospital.

Response: We disagree with the commenters who argue that the proposed policy would exceed the Secretary's authority under the statute by

inappropriately varying payments for drugs by "hospital group" because we rely on section 1833(t)(14)(A)(iii)(II) of the Act, even though the explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II). As noted above, we believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust payment rates according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Although we acknowledge that hospitals are eligible to receive drugs at discounted rates under the 340B Program if they qualify as a "covered entity" for purposes of the 340B Program, not all drugs for which a covered entity submits a claim for payment under the OPPS are necessarily acquired under the 340B Program. The OPPS payment for those drugs not acquired under the 340B Program would continue to be paid at ASP+6 percent.

We also note generally that the OPPS statute authorized the Secretary to establish appropriate Medicare OPPS payment rates for covered outpatient drugs. After specifically setting forth the payment methodology for 2004 and 2005, Congress provided that the Secretary could set OPPS drug prices in one of two ways: Using the average acquisition cost for the drug for that year, or using the average price for that drug in the year. However, in either case, prices set using either benchmark may be adjusted by the Secretary. Such adjustments may occur under section 1833(t)(14)(A)(iii)(II) of the Act if the Secretary determines they are "necessary for purposes of" section 1833(t)(14) of the Act, and this paragraph of

the Medicare OPPS statute repeatedly discusses terms like "hospital acquisition cost" and "variation in hospital acquisition costs", and specifically notes in one section that it is within the Secretary's authority to determine that the payment rate for one drug "may vary by hospital group." It would be odd for Congress to have a significant delegation of authority to the Secretary, use these specific terms and considerations throughout section 1833(t)(14) of the Act, and then assume the Secretary is foreclosed from taking into account those considerations in adjusting ASP "as necessary for purposes" of section 1833(t)(14) of the Act. The Secretary is generally empowered to adjust drug prices "as necessary" for the overall purposes of section 1833(t)(14) of the Act, and there is nothing in section 1833(t)(14) of the Act to indicate the Secretary is foreclosed from varying Medicare OPPS payment for a drug, depending on whether a 340B hospital acquired that drug at such a substantially lower acquisition cost.

• *Authority To Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority To Base Payment on an Average Discount*

Comment: Some commenters, including a commenter representing teaching hospitals, stated that the Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs. In addition, the commenters stated that section 1833(t)(14) of the Act requires the Secretary to rely on an average of acquisition cost data and sales prices for a given drug, not an average discount that is applied to all drugs acquired under the 340B Program.

One commenter stated that the Secretary impermissibly conflates the two alternative methods for setting payment rates, "essentially discarding Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys." This commenter asserted that the Secretary is using MedPAC's estimate of average discounts as a proxy or replacement for the surveys required under subsection (iii)(I).

Response: We disagree that section 1833(t)(14)(A)(iii)(II) of the Act requires use of survey data and note that, unlike subclause (I) of this section, subclause (II) does not require taking survey data into account for determining average price for the drug in the year. We continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Moreover, under section 1833(t)(14)(A) of the Act, there still will be one starting, baseline price for an applicable drug, that is, the rate that applies under 1842(o), 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary. For drugs not acquired under the 340B Program, we will continue to utilize that price (ASP+6 percent), which as we have explained "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals." However, for drugs acquired through the 340B Program, we are adjusting that price downward (ASP minus 22.5 percent) to more closely align with the hospital acquisition cost for a drug when purchased at a discounted price under the 340B Program. In the absence of acquisition costs from hospitals that purchase drugs through the 340B Program, we believe

it is appropriate to exercise our authority to adjust the average price for 340B-acquired drugs, which are estimated to be acquired at an average minimum discount of ASP minus 22.5 percent. Importantly, because we are not using authority under section 1833(t)(14)(A)(iii)(I) of the Act (as the commenter suggested), we disagree with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

• *Current Agency View Contrasts With Longstanding Practice*

Comment: Some commenters contended that the proposal contrasts sharply with the agency's previous view and longstanding practice of applying the statutory scheme of section 1833(t)(14) of the Act. These commenters noted that since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never invoked the discretionary authority. The commenters stated that, instead, CMS stated that the statutory default of ASP+6 percent "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals." Moreover, the commenters added, CMS has applied the statutory default rate without further adjustment in each subsequent year. They asserted that the CY 2018 proposal, in contrast, departs dramatically from longstanding prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent for drugs acquired under a 340B Program.

Response: As discussed in the earlier background section, section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary authority to adjust, as necessary for purposes of paragraph (14) of section 1833(t) of the

Act, the applicable payment rate for separately payable covered outpatient drugs under the OPPS. Specifically, we believe that the proposed reduced payment for 340B-acquired drugs would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph* (paragraph (14) of section 1833(t) of the Act) (emphasis added). We do not have hospital acquisition cost data for 340B drugs and, therefore, we proposed to continue to pay for these drugs under the methodology in our authority at section 1833(t)(14)(A)(iii)(II) of the Act which we determined to be ASP, and then to adjust that amount by applying a reduction of 22.5 percent to that payment methodology, which, as explained throughout this section, is the adjustment we believe is necessary to more closely align with the acquisition costs for drugs acquired under the 340B Program.

As previously stated, we believe that using an average discount to set payment rates for separately payable 340B-acquired drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs and (2) protecting the confidential nature of discounts applied to a specific drug. Furthermore, our proposed and finalized policy will lower OPPS payment rates for Medicare beneficiaries who receive drugs at hospitals subject to the 340B payment reduction.

In addition, we do not believe that the fact that we have not historically utilized our adjustment authority

under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs means we are permanently barred from adjusting these payments where, as here, we have provided a reasoned explanation for doing so. We continue to believe, as the commenter noted, that ASP+6 percent requires no further adjustment for drugs that are not acquired under the 340B Program because, at this time, we have not found similar evidence of the difference between the statutory benchmark (ASP+6 percent) and average hospital acquisition costs for such drugs. However, that is not the case for 340B-acquired drugs. As explained in detail throughout this section, we believe that a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment, for drugs acquired under the 340B Program, is necessary for Medicare OPPS payment policy.

• *Violation of Section 340B of the Public Health Service Act*

Comment: Some commenters stated that the proposed payment reduction would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts. One commenter asserted that the payment proposal would "hijack Congress' carefully crafted statutory scheme by seizing 340B discounts from hospitals and transferring the funds to providers that Congress excluded from the 340B Program," thereby violating section 340B of the Public Health Service Act. The commenter further noted that discounts under the 340B Program are only available to "covered entities" that are defined by law and that Congress thus intended the benefits of the program to accrue to these

providers only. The commenter contended that Congress' reference to Medicare definitions when describing covered entities demonstrates that it considered the Medicare program when it adopted the 340B Program and decided not to grant discounts to all Medicare hospitals. Rather, the commenter believed that Congress made a deliberate decision to limit the benefits of the 340B Program only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients. In addition, the commenter stated that when Congress has intended Federal health care programs to intrude upon the 340B Program, it has been crystal clear.

In contrast, commenters asserted that Congress has been wholly silent on the relationship between 340B and Medicare Part B, which indicates Congress's intent that Medicare should not "encroach" upon the 340B Program by "redistributing [340B] discounts to non-340B providers." The commenters noted that the 340B statute and Medicare have coexisted for several years and that Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. As an example, the commenters cited legislation enacted in 2010, in which Congress amended both the 340B and the Medicare statutes, but did not authorize CMS to redistribute 340B savings to non-340B hospitals or to Part B generally.

Commenters further asserted that the proposed cut to 340B hospitals is also contrary to Congress's intent for the 340B Program to enable safety-net providers to reach more patients and furnish more comprehensive services and would undermine this purpose by preventing the operation of the 340B statute. These

commenters suggested that, although manufacturers would still have to give 340B discounts, 340B participating hospitals would receive no benefit from those discounts; thus, the statutory purpose of 340B would be fatally undermined.

Response: We do not believe that this proposal under section 1833(t) of the Act is in conflict with section 340B of the Public Health Service Act. Section 1833(t) of the Act governs Medicare payment policies for covered hospital outpatient department services paid under the OPPS, while section 340B of the Public Health Service Act governs eligibility and program rules for participation in the 340B Program. There are no references in either section of law to each other. In fact, the failure of either statute to reference the other proves the opposite—that each statute stands on its own and neither is hindered or rendered null and void by the other. There is no requirement in the Public Health Service Act that the 340B Program "guarantee" or provide a certain profit from the Medicare program. Likewise, there is no requirement in section 1833(t) of the Act to pay a particular rate for a hospital enrolled in the 340B Program. We agree with the commenters that Congress was aware of both the 340B Program and the OPPS and of the programs' relationships to one another. However, we believe that the silence of each statute with respect to the other should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPS.

Furthermore, we are unaware of legislative history or other evidence to corroborate the commenters' belief that Congress' silence on the relationship between 340B and Medicare Part B OPPS payments should be

viewed as constraining the Secretary's ability under section 1833(t)(14) of the Act as to how to calculate payment rates for drugs acquired under the 340B Program under the OPPS. While legislative silence can be difficult to interpret, we note that Congress' silence regarding the 340B Program in enacting Medicare OPPS payment for certain drugs would create the opposite inference. The 340B Program existed well before Congress enacted the Medicare OPPS and payment for certain drugs. If Congress wanted to exempt 340B drugs or entities with a 340B agreement from Medicare OPPS payment for drugs generally, it easily could have done so. Instead, Congress provided for Medicare OPPS drug payments "as calculated and adjusted by the Secretary as necessary," without any mention of, or restriction regarding, the already existent 340B Program.

We also disagree with commenters who believe that implementing the OPPS payment methodology for 340B-acquired drugs as proposed will "eviscerate" or "gut" the 340B Program. As discussed earlier in the background section, the findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. As stated in the proposed rule, we believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program.

With respect to the comment that the proposal would frustrate the intent of the 340B Program and redirect Medicare payments to other hospitals that do

not participate in the 340B Program, we reiterate that we proposed to redistribute the savings in an equal and offsetting manner to all hospitals paid under the OPPS, including those in the 340B Program, in accordance with the budget neutrality requirements under section 1833(t)(9)(B) of the Act. However, we remain interested in exploring ways to better target the offsetting amount to those hospitals that serve low-income and uninsured patients, as measured by uncompensated care. Details on the redistribution of funds are included in section XVIII. of this final rule with comment period.

• Proposal Is Procedurally Defective and Inconsistent With Advisory Panel Recommendations

Comment: Some commenters contended that the proposal is procedurally defective under the OPPS statute. The commenters asserted that the Secretary's justification for the proposed reduced rate rests, in part, on intertwined issues related to clinical use and hospital cost of drugs. The commenters objected to CMS' reference to studies suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals as support for proposing a payment rate that eliminates the differential between acquisition cost and Medicare payment. These commenters cited other studies in an effort to refute

the evidence presented in the proposed rule.[29] [30] The commenters believed that CMS should have asked the HOP Panel to consider the intertwined issues of drug cost and clinical use prior to making a proposal to reduce payment for 340B-acquired drugs, and the Secretary should have consulted with the HOP Panel in accordance with section 1833(t)(9)(A) of the Act, as part of the process of review and revision of the payment groups for covered outpatient department services and the relative payment weights for the groups. The commenters argued that, because the Secretary did not consult with the HOP Panel before publishing its 340B payment proposal, the Secretary acted contrary to the statute. The commenters noted that at the August 21, 2017 meeting of the HOP Panel that occurred after publication of the proposed rule, the Panel urged that CMS not finalize the proposed payment reduction.

At the August 21, 2017 meeting of the HOP Panel, the Panel made the following recommendations with respect to the proposed policy for OPPS payment for drugs acquired under the 340B Program:

The Panel recommended that CMS:

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[29] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: *http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf*.

[30] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: *http://www.340bhealth.org/files/LowIncomeOncology.pdf*;

• Not finalize its proposal to revise the payment rate for drugs purchased under the 340B Program;

• Collect data from public comments and other sources, such as State Medicaid programs in Texas and New York, on the potential impact of revising the payment rate, implementing a modifier code, and the effects of possible mechanisms for redistributing the savings that result from changing the payment rate; and

• Assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

In addition, one commenter suggested that the proposal was "procedurally defective" because the proposal was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR). The commenter asserted that the proposal cannot be implemented without a change to the Medicare regulations and stated that the Medicare statute requires CMS to issue regulations when altering the substantive standards for payment.[31] The commenter stated that the proposal falls squarely within this requirement because it would change the substantive legal standard governing payments to 340B hospitals for separately payable drugs.

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[31] "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation. . . ." Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

Another commenter stated that CMS' proposal also violates section 1833(t)(2)(E) of the Act because the agency is not authorized and did not offer a reasoned basis for applying savings achieved as a result of its proposal to reduce significantly payments to 340B hospitals to Part B services generally. Likewise, a few commenters stated that the Administrative Procedure Act (APA) requires the Secretary to offer a "reasoned basis" for proposing to take an unprecedented action. The commenters suggested that, as a matter of longstanding policy and practice, the Secretary has never applied such a sweeping change to drug rates nor has it ever applied savings from OPPS outside of the OPPS.

Response: We remind the commenters that our proposal was based on findings that ASP minus 22.5 percent reflects the minimum average discount that hospitals in the 340B Program receive. We are familiar with the reports the commenters referenced in their comments. However, we continue to believe, based on numerous studies and reports, that 340B participation is not well correlated to the provision of uncompensated care and is associated with differences in prescribing patterns and drug costs. For example, as noted earlier in this section, GAO found that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals," thus indicating that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis.

With respect to the HOP Panel, we believe that this comment reflects a misunderstanding of the Panel's

role in advising the Secretary. Section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

The provisions described under section 1833(t)(9)(A) of the Act do not impose an obligation on the Secretary to consult with the HOP Panel prior to issuing a notice of proposed rulemaking nor do they require the Secretary to adopt the Panel's recommendation(s). Rather, the statute provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Secretary met the requirement of section 1833(t)(9)(A) of the Act at the HOP Panel August 21, 2017 meeting in which the Panel made recommendations on this very proposed policy. The HOP Panel's recommendations, along with public comments to the proposed rule, have all been taken into consideration in the development of this final rule with comment period.

While we are not accepting the HOP Panel's recommendation not to finalize the payment reduction for drugs purchased under the 340B Program, as discussed later in this section, we are modifying our position on the modifier in an effort to ease administrative burden on providers, taking into account the way in which the modifier is used in several State Medicaid programs, as the Panel

recommended. In addition, we have collected data from public comments on the potential impact of revising the payment rate, implementing a modifier, and the effects of possible mechanisms for redistributing the "savings" (or the dollars that result) from changing the payment rate and have assessed the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved, all of which were steps the HOP Panel recommended we take.

Regarding the comments asserting that the Secretary is out of compliance with procedures used to promulgate regulations as described under section 1871 of the Act (42 U.S.C. 1395hh), we note that we have received public comments on our interpretation of the Medicare statute, and we respond to those comments above. We further note that we did not establish in the Code of Federal Regulations the rates for separately payable, nonpass-through drugs and biologicals in past rulemakings. Because we have not adopted regulation text that prescribes the specific payment amounts for separately payable, nonpass-through drugs and biologicals, there was no regulation text to amend to include our proposed payment methodology for drugs acquired under the 340B Program. However, this does not mean that payment rates for separately payable drugs were not available to the public. That information is available in Addendum B to this final rule with comment period, which lists the national payment rates for services paid under the OPPS, including the payment rates for separately payable drugs and biologicals based on ASP+6 percent. We note that we have not provided the reduced payment rates for separately payable drugs and biologicals acquired under the 340B Program in Addendum B, but hospitals can arrive at those rates

using the ASP+6 percent rate that is included in Addendum B. Finally, with respect to comments on redistribution of the dollars that result from the 340B payment policy, we are finalizing our proposal to achieve budget neutrality for the payment reduction for 340B-acquired drugs through an increase in the conversion factor. We disagree that our proposal to apply budget neutrality in accordance with section 1833(t)(9)(B) of the Act violates the APA or statutory authority. Further, we note that if we decide to take a different approach with respect to the redistribution of funds for budget neutrality in the future, we will consider such approach in future rulemaking.

• Impact on Medicare Beneficiary Cost-Sharing

Comment: Some commenters noted that Medicare beneficiaries, including dual-eligible Medicare beneficiaries, would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part. These commenters asserted that the proposal would actually increase their out-of-pocket costs for other Part B benefits.

Response: The cost-sharing obligation for Medicare beneficiaries is generally 20 percent of the Medicare payment rate. While many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on behalf of the beneficiary. While we are implementing this policy in a budget neutral manner equally across the OPPS for CY 2018 for non-drug items and services, we may

revisit how any savings from the lowered drug payment rate for 340B drugs may be allocated in the future and continue to be interested in ways to better target the savings to hospitals that serve the uninsured and low-income populations or that provide a disproportionate share of uncompensated care.

In addition, as noted earlier in this section, in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a "facility fee" solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 drug administration services and believe that these steps taken together may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

• *Calculation of Savings*

Comment: Commenters disagreed with CMS' impact estimate and a few commenters provided their own analysis of the 340B drug payment proposal. One commenter believed that even if CMS implements the policy as proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, payments for non-drug APCs would increase across hospitals by approximately 3.7 percent (in contrast to CMS' estimate of 1.4 percent). According to the commenter, this redistribution would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million. The commenter asserted that CMS' proposal would remove $800 million intended to support what it referred to as the congressionally mandated mission

of 340B hospitals from these already vulnerable facilities and redistribute these dollars to other hospitals that do not participate in the 340B Program. Likewise, the commenter challenged CMS' suggested alternative approaches to achieving budget neutrality, such as applying offsetting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as to physician services under the Medicare Physician Fee Schedule), which the commenter believed would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B Program. Finally, other commenters noted that implementing the proposed policy in a non-budget neutral manner would effectively "gut" the 340B Program.

Response: With respect to comments on the proposed distribution of savings, we refer readers to section XVIII. of this 2018 OPPS/ASC final rule with comment for discussion on the redistribution of savings that result from the estimated impact of the 340B policy as well as calculation of budget neutrality. Briefly, for CY 2018, we are implementing the alternative payment methodology for drugs purchased under the 340B Program in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor for nondrug services. Therefore, the resulting savings from the 340B payment policy will be redistributed pro rata through an increase in rates for non-drug items and services under the OPPS. We have already addressed comments relating to the assertion that our proposal would "gut" or "eviscerate" the 340B Program. Likewise, we have addressed the interaction between our authority under section 1833(t)(14)(A) of the Act relative to section 340B of the Public Health Service Act in our responses above.

(3) Other Areas

Comment: MedPAC commented reiterating its recommendations to Congress in its March 2016 Report to the Congress. Specifically, MedPAC commented that it recommended that payment rates for all separately payable drugs provided in a 340B hospital should be reduced to 10 percent of the ASP rate (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to the Congress that savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured, and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status.

Response: We thank MedPAC for its comments and for its clarification that its recommendation that "[t]he Congress should direct the Secretary of the Department of Health and Human Services to reduce Medicare payment rates for 340B hospitals' separately

payable 340B drugs by 10 percent of the average sales price (ASP)" was intended to be 10 percent lower than the current Medicare rate of ASP+6 percent and would result in a final OPPS payment of ASP minus 5.3 percent when taking the sequester into account. However, we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B participating hospitals. In its May 2015 Report to the Congress, MedPAC estimated that the average minimum discount for a 340B hospital paid under the OPPS was ASP minus 22.5 percent, which it noted was a conservative, "lower bound" estimate. Further, in its March 2016 Report to the Congress, MedPAC stated that, "[i]n aggregate, the Office of Inspector General (OIG) estimates that discounts across all 340B providers (hospitals and certain clinics) average 34 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs (MedPAC March 2016 Report to Congress, page 76). MedPAC further noted the estimate of the aggregate discount was based on all covered entities (hospitals and certain clinics). Because 340B hospitals accounted for 91 percent of Part B drug spending for all covered entities in 2013, it is reasonable to assume that 340B hospitals received a discount similar to 33.6 percent of ASP (MedPAC March 2016 Report to Congress, page 79).

Further, as we stated in the proposed rule, the GAO reported that the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, voluntary participation in the PVP results in a covered entity paying a subceiling price on certain covered outpatient

drugs (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification)

Accordingly, we continue to believe that ASP minus 22.5 percent represents a conservative estimate of the average minimum discount that 340B-enrolled hospitals paid under the OPPS receive for drugs purchased with a 340B Program discount and that hospitals likely receive an even steeper discount on many drugs, especially brand name drugs. We also continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act allows the Secretary to make adjustments, if hospital acquisition cost data is not available, as necessary, so that the Medicare payment rate better represents the acquisition cost for drugs and biologicals that have been acquired with a 340B discount.

With respect to MedPAC's comment regarding targeting the savings to uncompensated care, we refer readers to section XVIII.A.5. of this final rule with comment period.

• Comments Regarding Rural Hospitals

Comment: Commenters representing rural hospitals, particularly RRCs and SCHs, expressed opposition to the proposal, noting that it could be especially harmful to rural hospitals in light of the "hospital closure crisis." One commenter cited a report from a health analytics company and noted that since 2010, 80 rural hospitals have closed and that one-third of remaining rural hospitals are vulnerable to closure, with 41 percent of rural hospitals operating at a financial loss.

Commenters noted that rural hospitals enrolled in the 340B Program depend on the drug discounts to

provide access to expensive, necessary care such as labor and delivery and oncology infusions. The commenters stated that rural Americans are more likely to be older, sicker, and poorer than their urban counterparts. The commenter gave examples of rural hospitals that have used profit margins on 340B-acquired drugs to offset uncompensated care and staff emergency departments. In addition, the commenters stated that a portion of rural hospitals are excluded from purchasing orphan drugs through the 340B Program. Therefore, the commenters stated, these hospitals often use their 340B savings to offset the expense of purchasing orphan drugs, which they note comprise a growing number of new drug approvals.

In addition, a commenter representing several 340B-enrolled hospitals stated that multiple hospitals report that the 340B Program is the reason the hospital can provide oncology infusions in their local community and that the chemotherapy infusion centers tend to be small with variation in patients served based on the needs of the community. The commenter stated that, without the 340B Program, many rural hospitals would likely need to stop providing many of the outpatient infusions, thereby forcing patients to either travel 35 miles (in the case of SCHs which must generally be located at least 35 miles from the nearest like hospital) to another facility or receive care in a hospital inpatient setting, which is a more costly care setting. Another commenter, a member of Congress representing a district in the State of Ohio, commented that while the 340B Program is in need of reform, the program remains an important safety net for rural hospitals in Ohio and around the country. The commenter stated that 340B hospitals offer safety-net programs to their communities, including opioid treatment programs,

behavioral health science programs, and others. The commenter further stated that the 340B drug payment proposal did not address broader structural issues with the 340B Program itself, including lack of oversight and clear guidance and definitions, and that the proposal could harm the hospitals that the 340B Program was intended to help. In addition, the commenter noted that "arbitrary cuts" to the 340B Program for safety-net hospitals could have detrimental impacts on the economic growth and opportunities in the communities those hospitals serve and that the proposal does not advance the larger goals of 340B Program reform.

One commenter noted that SCHs face 47.5 percent higher levels of bad debt and 55 percent lower profit margins. Thus, even with 340B discounts, the commenter argued that rural hospitals like rural SCHs are financially threatened. Commenters also noted that rural hospitals are typically located in lower income economic areas and are not able to absorb the proposed reduction in drug payment for 340B purchased drugs. Moreover, commenters suggested that the proposal disproportionately impacts rural hospitals compared to its effect on urban hospitals.

Finally, commenters requested that, if CMS finalizes the policy as proposed, CMS exempt hospitals with a RRC or SCH designation from the alternative 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as "economic engines" for many rural communities.

Response: We share commenters' concerns about access to care, especially in rural areas where access

issues may be even more pronounced than in other areas of the country. We note our proposal would not alter covered entities' access to the 340B Program. The alternative 340B drug payment methodology solely changes Medicare payment for 340B-acquired drugs.

Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

In the CY 2018 OPPS/ASC proposed rule, we sought public comment for future policy refinements on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments for drugs acquired under the 340B program. Taking into

consideration the comments regarding rural hospitals, we believe further study on the effect of the 340B drug payment policy is warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. In particular, given challenges such as low patient volume, it is important that we take a closer look at the effect of an ASP minus 22.5 percent payment on rural SCHs.

With respect to RRCs, we note that there is no special payment designation for RRCs under the OPPS. By definition, RRCs must have at least 275 beds and therefore are larger relative to rural SCHs. In addition, RRCs are not subject to a distance requirement from other hospitals. Accordingly, at this time, we are not exempting RRCs from the 340B payment adjustment.

For CY 2018, we are excluding rural SCHs (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in the CY 2019 OPPS rulemaking.

• Children's and PPS-Exempt Cancer Hospitals

Comment: Commenters representing children's hospitals ("children's") raised objections to the proposal because of the potential impact on the approximate 8,000 children with end-stage renal disease (ESRD) who are eligible for Medicare. One commenter cited that currently 48 children's hospitals participate in the 340B Program and rely on the savings the program provides to enhance care for vulnerable children. According to the commenter, pediatric ESRD patients require high levels of care and rely on life-saving pharmaceuticals that often

come at a high cost. Therefore, the commenters posited that it is because children's patients are more expensive to treat and not because of inappropriate drug use that 340B hospitals incur higher drug expenditures. In addition, the commenters expressed concern with the effect the 340B drug payment policy may have on State Medicaid programs, considering Medicaid is the predominant payer type for children's hospitals. The commenters requested that, unless CMS is able to examine the impact on pediatric Medicare beneficiaries, CMS should exempt children's hospitals from the alternative 340B drug payment methodology.

An organization representing PPS-exempt cancer hospitals commented that CMS' proposal would severely harm the hospitals that treat the most vulnerable and underserved patients and communities, undermining these hospitals' ability to continue providing programs designed to improve access to services. The commenter believed that assumptions alluded to in the CY 2018 OPPS/ASC proposed rule, which suggested that providers are abusing the savings generated from the 340B Program or potentially creating incentives to over utilize drugs, are inaccurate and that clinicians provide the care that is necessary to treat a patient's disease. The commenter suggested that CMS work with, or defer to, HRSA to first conduct a complete analysis of how the 340B Program is utilized for the benefit of patients prior to proposing any changes to Medicare payment for drugs purchased through the program.

Response: We share the commenters' views on protecting access to high quality care for all Medicare beneficiaries, including those treated in children's or PPS-exempt cancer hospitals. Further, because of how

these classes of hospitals are paid under the OPPS, we recognize that the 340B drug payment proposal may not result in reduced payments for these hospitals in the aggregate.

Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. That is, these hospitals are permanently held harmless to their "pre-BBA amount," and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure.

Accordingly, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology for CY 2018. Therefore, for CY 2018, we are excluding children's and PPS-exempt cancer hospitals from the alternative 340B drug payment policy. As discussed in a later section in this final rule with comment period, because we are redistributing the dollars in a budget neutral manner within the OPPS through an offsetting increase to the conversion factor, children's hospitals and PPS-exempt cancer hospitals will receive a higher payment when providing a non-drug service.

In summary, we are adopting for CY 2018 an exemption for rural SCHs, children's hospitals, and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology. These three types of

hospitals will not be subject to a reduced drug payment for drugs that are purchased under the 340B Program in CY 2018. We may revisit the specific types of hospitals excluded, if any, from the 340B payment policy in CY 2019 rulemaking. However, as discussed in more detail below, it remains important to collect information on which drugs being billed to Medicare were acquired under the 340B Program. Accordingly, these three types of hospitals will still be required to report an informational modifier "TB" for tracking and monitoring purposes. We may revisit this 340B drug payment policy, including whether these types of hospitals should continue to be excepted from the reduced Medicare payment rate, in future rulemaking.

• Biosimilar Biological Products

Comment: Some commenters expressed opposing views about applying the proposed 340B payment methodology to biosimilar biological products. One pharmaceutical manufacturer recommended that the Secretary use his equitable adjustment authority at section 1833(t)(2)(E) of the Act to apply a narrow equitable adjustment to biosimilar biological products with pass-through payment status to pay for these drugs at ASP minus 22.5 percent of the reference product rather than ASP+6 percent of the reference product. The commenter asserted that excluding biosimilar biological products from the alternative 340B payment methodology would result in a significant payment differential between biosimilar biological products and reference products which may cause providers to switch patients to different products for financial reasons, rather than clinical factors. The commenter stated that, if the policy is implemented as proposed, the competitive biosimilar marketplace would significantly change because

Medicare would pay more for the biosimilar biological product with pass-through payment status and weaken market forces. The commenter estimated that if the 340B drug policy is implemented as proposed, up to $50 million of any savings could be lost due to hospitals switching to the biosimilar biological product on pass-through payment status (that will be paid at ASP+6 percent of the reference product). Moreover, the commenter pointed out that CMS' policy to only provide pass-through payments for the first eligible biosimilar biological product of any reference biological would also create a similar payment disadvantage for any subsequent biosimilar biological product, which would be ineligible for pass-through payment under CMS' policy.

Another commenter, a different pharmaceutical manufacturer, requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established. The commenter indicated that while a biosimilar biological product is less expensive to the Medicare program, hospitals are incented by the 340B Program to purchase the originator product because of "the spread" or payment differential with respect to the originator product. Moreover, the commenter stated that applying the proposed adjustment to payment for biosimilar biological products in certain hospitals will retain market share for the more expensive reference product that is further compounded by market practices of volume-based rebates and exclusionary contracts for the reference product.

Response: We understand the commenters' concerns. As discussed in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period, we

are adopting the biosimilar biological products HCPCS coding established under the CY 2018 MPFS final rule. Briefly, we adopted a final policy to establish separate HCPCS codes for each biosimilar biological product for a particular reference product beginning January 1, 2018. In addition, we also stated in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period that we are making a conforming amendment to our pass-through payment policy for biosimilar biological products such that each FDA-approved biosimilar biological product will be eligible for transitional pass-through payment instead of only the first biosimilar for a particular reference product.

Therefore, given the policy changes affecting coding and payment for biosimilar biological products that we are adopting in the CY 2018 MPFS final rule and this CY 2018 OPPS/ASC final rule with comment period, we disagree with the commenters that we should exclude biosimilar biological products from the 340B payment policy or use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adjust payment to ASP minus 22.5 percent of the reference product for biosimilar biological products with pass-through payment status. We believe the statutory provision on transitional drug pass-through payment under section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs eligible for pass-through payment. Therefore, we are unable to accept the commenter's request to pay a biosimilar biological product on pass-through payment status the reduced 340B payment rate. We are adopting a policy that any biosimilar biological product with pass-through payment status will be exempt from the alternative payment methodology for 340B drugs and will continue to be paid at ASP+6 percent of the reference product. Biosimilar biological products that

are not on pass-through payment status will be paid ASP minus 22.5 percent of the reference product. We believe it is appropriate to pay this amount for biosimilar biological products as it is consistent with the amount paid for non-340B-acquired biosimilar biological products, which is ASP+6 percent of the reference product. Currently, there are two biosimilar biological products available on the market and both are on pass-through payment status for the entirety of CY 2018. Therefore, no biosimilar biological products currently available will be affected by the alternative payment methodology for 340B-acquired drugs for CY 2018. We recognize the concerns about paying different rates for similar drugs and biologicals and continue to assess the feasibility and practicality of an alternative 340B payment adjustment for biosimilar biological products in the future.

• Nonexcepted Off-Campus Hospital Outpatient Departments

Comment: A few commenters noted that CMS' proposed alternative payment methodology for 340B purchased drugs would not apply to nonexcepted off-campus provider-based departments (PBDs) of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Bipartisan Budget Act of 2015. Commenters recommended that, if CMS adopts a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs are acquired under the 340B Program. In addition, the commenters believed that because CMS did not propose to limit the expansion of

services or volume increases at excepted off-campus PBDs, CMS will create financial incentives for hospitals to shift or reallocate services to the site of care that pays the highest rate for an item or service.

Response: We appreciate the commenter's concerns about potential unintended consequences of our proposal. We will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs as we continue to explore whether to pursue future rulemaking on the issues of clinical service line expansion or volume increases, and other related section 603 implementation policies.

In the CY 2017 OPPS/ASC final rule with comment period, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 144–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered outpatient department services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met (81 FR 79699). We issued an interim final rule with comment period along with the CY 2017 OPPS/ASC final rule with comment period to establish the MPFS as the "applicable payment system," which will apply in most cases, and payment rates under the MPFS for non-excepted items and services furnished by nonexcepted off-

campus outpatient provider based departments (PBDs) (81 FR 79720). (Other payment systems, such as the Clinical Laboratory Fee Schedule, continue to apply in appropriate cases.) That is, items and services furnished by nonexcepted off-campus outpatient PBDs, are nonexcepted items and services that are not covered outpatient services, and thus, are not payable under the OPPS. Rather, these nonexcepted items and services are paid "under the applicable payment system," which, in this case, is generally the MPFS.

As we discussed in the CY 2017 OPPS/ASC interim final with comment period (81 FR 79718) and reiterated in the CY 2018 MPFS final rule, payment for Part B drugs that would be separately payable under the OPPS (assigned status indicator "K") but are not payable under the OPPS because they are furnished by nonexcepted off-campus outpatient PBDs will be paid in accordance with section 1847A of the Act (generally, ASP+6 percent), consistent with Part B drug payment policy in the physician office. We did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking.

• Data Collection and Modifier

Comment: The vast majority of commenters objected to CMS' intention to require hospitals that *do not* purchase a drug or biological through the 340B program to apply a modifier to avoid a reduced drug payment. A few commenters supported the modifier proposal. The commenters who disagreed with proposal stated that it would place an unnecessary administrative and financial burden on hospitals that do not participate or are not eligible to participate in the 340B Program. Similarly, the commenters stated

that the modifier requirement as described in the proposed rule would put a financial and administrative strain on hospitals with fewer resources. In addition, the commenters contended that a requirement for hospitals to report a modifier for drugs that were not acquired under the 340B Program would place hospitals at significant risk for noncompliance if not implemented correctly, which many commenters believe is nearly impossible to do. As an alternative approach, numerous commenters recommended that CMS require hospitals that *do* purchase a drug under the 340B Program to report the modifier, rather than those that do not.

Regarding a January 1, 2018, implementation date for the modifier, some commenters expressed concern and doubted their ability to implement the modifier as described in the proposed rule accurately. The commenters indicated that additional time would be needed to adapt billing systems, allow for testing of claims reported with the modifier, and educate staff. Based on discussion of how the modifier would work in the proposed rule, the commenters stated that hospitals would either have to append the modifier to the claim at the time the drug is furnished, or retroactively apply the modifier, thus delaying claims submission to Medicare.

The commenters provided detailed descriptions on hospital pharmacy set up, including information on software tools to support inventory management of drugs dispensed to 340B and non-340B patients (based on HRSA definition of an eligible patient). One commenter indicated that the drug supply system used for purchasing covered outpatient drugs is completely separate from—and does not necessarily communicate with—the hospital's pharmacy drug

dispensing and patient billing systems. While these software tools enable split-billing to distinguish 340B and non-340B patients, the commenters noted that this patient determination is typically not done in real time when a drug is administered. Commenters noted that 340B hospitals that use split-billing software do not receive information on 340B patient status on a daily basis and the proposal could result in delayed billing. The commenters stated that hospitals typically make these determinations retrospectively and it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. The commenters noted that, under this "replenishment model," hospitals track how many 340B-eligible drugs are used, and once enough drugs are dispensed to complete a package, they will replenish the drug at the 340B rate. As such, the commenters argued that hospitals do not know when the drug is dispensed whether it will cost them the 340B rate or the wholesale acquisition cost (WAC). Therefore, the commenters expressed concern that the modifier requirement as described in the proposed rule would result in billing delays and, for some hospitals, may cause a short-term interruption in cash flow.

In addition, the commenters requested that, while the payment reduction would apply to nonpass-through separately payable drugs purchased with a 340B discount, CMS accept the modifier when reported with drug HCPCS codes that are packaged (and for which no separate payment will be made) to reduce or prevent operational burden that may be caused if affected providers have to determine on a claim-by-claim basis whether a drug is eligible for separate payment.

With respect to State Medicaid programs that also require a modifier to identify 340B-purchased drugs on outpatient claims, the commenters noted that CMS' proposal would be counter to Medicaid requirements and would create confusion and add complexity for providers who treat Medicaid recipients in multiple states. The commenters reported that many State Medicaid programs require a modifier to identify drugs that were purchased under 340B to administer their Medicaid drug rebate programs to prevent duplicate discounts on 340B drugs. The commenters suggested that if CMS reversed its position on application of the modifier, it would ensure crossover claims (claims transferred from Medicare to Medicaid) are correctly interpreted by State Medicaid programs so that they can appropriately request manufacturer rebates on drugs not purchased under the 340B Program. Moreover, some commenters believed that if CMS required the modifier to be reported for 340B-purchased drugs, State Medicaid programs would also adopt the modifier, leading to national uniformity in reporting of 340B drugs.

Finally, in the event that CMS required the modifier on claims for 340B drugs, rather than non-340B drugs, commenters sought clarity on whether the modifier applies only to drugs purchased under the 340B Program which are subject to a ceiling price payment from the manufacturer or if the modifier would also apply to drugs purchased by a 340B-registered facility, but purchased under the Prime Vendor Program for which only 340B facilities are eligible. One commenter asked that CMS emphasize that 340B pricing is not available on drugs furnished to hospital inpatients.

Response: We appreciate the detailed comments that were submitted. As noted in the proposed rule, we did not propose to establish the modifier but rather noted our intent to establish the modifier, regardless of whether we adopted the alternative payment methodology for drugs acquired through the 340B Program. However, we are responding to some of the comments submitted in this final rule with comment period with information on this modifier that we believe is important to communicate as soon as possible. We will consider whether additional details will need to be communicated through a subregulatory process, such as information posted to the CMS Web site.

After considering the administrative and financial challenges associated with providers reporting the modifier as described in the CY 2018 OPPS/ASC proposed rule, and in order to reduce regulatory burden, we are reversing our position on how the modifier will be used by providers to effectuate the payment adjustment for 340B-purchased drugs.

Specifically, beginning January 1, 2018, providers who are not excepted from the 340B payment adjustment will report modifier "JG" (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program. This requirement is aligned with the modifier requirement already mandated in several States under their Medicaid programs. Therefore, we believe that this option will pose less of an administrative burden. Further, having consistent application of the modifier being required for a drug that was purchased under the 340B Program instead of a drug not purchased under the 340B Program will help improve program integrity by helping ensure that

hospitals are not receiving "duplicate discounts" through both the Medicaid rebate program and the 340B Program. The phrase "acquired under the 340B Program" is inclusive of all drugs acquired under the 340B Program or PVP, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program should not be reported with the modifier "JG". For separately payable drugs (status indicator "K"), application of modifier "JG" will trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 22.5 percent. In response to the commenters' request that we allow the 340B modifier to be reported with status indicator "N" drugs (that is, drugs that are always packaged), we will accept modifier "JG" or "TB" to be reported with a packaged drug (although such modifier will not result in a payment adjustment).

In addition, beginning January 1, 2018, providers that are excepted from the 340B drug payment policy for CY 2018, which include rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier "JG". Instead, these excepted providers should report the informational modifier "TB" (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier "TB" will facilitate the collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018. However, use of modifier "TB" will not trigger a payment adjustment and these providers will receive ASP+6 percent for separately payable drugs furnished in CY 2018, even if such drugs were acquired under the 340B Program.

For drugs administered to dual-eligible beneficiaries (that is, beneficiaries covered under both Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program, the State Medicaid programs should be aware of modifier "JG" to help further prevent inappropriate billing of manufacturer rebates.

With respect to comments about timing to operationalize a modifier, we note that hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 13, 2017 that we intended to establish a modifier to implement the policy for payment of drugs acquired under the 340B Program, if finalized. In addition, the modifier will not be required until January 1, 2018, which after display of this final rule with comment period will give hospitals two additional months to operationalize the modifier. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Further, to the extent many hospitals already report a modifier through their State Medicaid program, we believe that also requiring the modifier on outpatient claims for 340B-acquired drugs paid for under the OPPS would not be a significant administrative burden and would promote consistency between the two programs. With respect to providers in States that are not currently required to report a modifier under the Medicaid program, we note that providers are nonetheless responsible for ensuring that drugs are furnished to "covered patients" under the 340B Program and, therefore, should already have

a tracking mechanism in place to ensure that they are in compliance with this requirement. Furthermore, modifiers are commonly used for payment purposes; in this case, the presence of the modifier will enable us to pay the applicable 340B drug rate of ASP minus 22.5 percent and track these claims in the Medicare data (in the case of "JG" modifier) and will allow us to track other drugs billed on claims that are not subject to the payment reduction (modifier "TB"). In addition, the presence of the both modifiers will enable Medicare and other entities to conduct research on 340B-acquired drugs in the future.

We remind readers that our 340B payment policy applies to only OPPS separately payable drugs (status indicator "K") and does not apply to vaccines (status indicator "L" or "M"), or drugs with transitional pass-through payment status (status indicator "G").

Finally, Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Medicare can also fine providers for knowingly, willfully, and repeatedly billing incorrectly coded claims. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

d. Summary of Final Policies for CY 2018

In summary, for CY 2018, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, separately payable Part B drugs (assigned status indicator "K"), other than vaccines and drugs on pass-through payment status, that meet the definition of "covered outpatient drug" as defined in the section 1927(k) of the Act, that are acquired through the 340B Program

or through the 340B PVP at or below the 340B ceiling price will be paid at the ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator "L" or "M") and drugs with OPPS transitional pass-through payment status (assigned status indicator "G"). Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP+6 percent.

Effective January 1, 2018, biosimilar biological products not on pass-through payment status that are purchased through the 340B program or through the 340B PVP will be paid at ASP minus 22.5 percent of the reference product's ASP, while biosimilar biological products on drug pass-through payment status will continue to be paid ASP+6 percent of the reference product.

To effectuate the payment adjustment for 340B-acquired drugs, CMS is implementing modifier "JG", effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or those hospitals paid under the Maryland waiver) or excepted from the 340B drug payment policy for CY 2018, are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final alternative 340B drug payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS for CY 2018. Specifically, the redistributed dollars will increase the conversion factor across non-drug rates by 3.2 percent for CY 2018.

We may revisit the alternative 340B drug payment methodology in CY 2019 rulemaking.

e. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount for 340B drugs. In the CY 2018 OPPS/ASC proposed rule (82 FR 33634 through 33635), we welcomed stakeholder input with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP minus 22.5 percent as the proposed payment rate for separately payable, nonpass-through OPPS drugs purchased under the 340B Program in CY 2018. We also requested comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPS drugs purchased under the 340B Program. Also, we sought comment on whether the proposal to pay ASP minus 22.5 percent for 340B-acquired drugs should be phased in over time (such as over a period of 2 to 3 years).

In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, we are interested in exploring ways to more

closely align the actual acquisition costs that hospitals incur rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. In the proposed rule, we requested public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim. Having the acquisition cost on a drug-specific basis would enable us to pay a rate under the OPPS that is directly tied to the acquisition costs for each separately payable drug. To the extent that the acquisition costs for some drugs may equal the ceiling price for a drug, we recognize that there may be challenges with keeping the ceiling price confidential as required by section 1927(b)(3)(D) of the Act and we sought comment on this point.

Lastly, for consideration for future policy refinements, we requested public comment on (1) whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments to 340B participating hospitals (if so, describe how adjusted rates for drugs purchased under the 340B Program would disproportionately affect access in these provider settings); (2) whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and (3) whether hospital-owned or affiliated ASCs have access to 340B discounted drugs.

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: One commenter recommended that CMS establish an exemption mechanism for use by stakeholders to request exemptions for certain groups of hospitals. The commenters urged CMS to propose and seek comment on specific guidelines that outline procedures for stakeholders to request an exemption and the criteria CMS would use to determine whether to grant an exception.

Response: We appreciate the comment. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. For CY 2018, as stated earlier in this section, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the alternative 340B drug payment methodology being adopted in this final rule with comment period. However, each of these excepted providers will report informational modifier "TB" on the same claim line as the HCPCS code for their 340B-acquired drugs.

Comment: In response to the solicitation of comments on whether CMS should exclude certain types of drugs from the proposed alternative 340B drug payment methodology, manufacturers of blood clotting factors and radiopharmaceuticals recommended that CMS continue to pay these drug types at ASP+6 percent. With respect to blood clotting factors, the commenters stated that individuals with bleeding disorders have unique needs and are expensive to treat such that the proposed reduced payment could threaten access and/or create unnecessary treatment delays for these patients. With respect to radiopharmaceuticals, the commenters stated that they do not believe that these products are covered outpatient drugs (because it is not possible for the manufacturer to accurately report final dose and

pricing information), and therefore these drugs should be excluded as a category of drugs included in the covered drug definition for the 340B Program.

In addition, one commenter recommended that CMS develop a process for stakeholders to request exemptions from the alternative 340B payment methodology that CMS would evaluate using objective patient guidelines designed to ensure patient access.

Response: We appreciate the comments. To the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B Program, we believe that the OPPS payment rate for these drugs should account for the discounted rate under which they were purchased. Therefore, for CY 2018, OPPS payment for separately payable, nonpass-through drugs, biologicals, and radiopharmaceuticals, including blood clotting factors and radiopharmaceuticals, if purchased through the 340B Program, will be paid at ASP minus 22.5 percent. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. We will consider these requests for exceptions for certain drug classes in development of the CY 2019 OPPS/ASC proposed rule.

It is unclear to us whether the commenter meant that radiopharmaceuticals are not considered covered outpatient drugs under the OPPS or not considered a covered outpatient drug for purposes of the 340B Program. We assume the commenter was referring to the definition of covered outpatient drug for purposes of the 340B Program and, as such, these comments are outside the scope of the CY 2018 OPPS/ASC proposed rule. We refer commenters to HRSA with questions related to the 340B Program.

Comment: One commenter representing community oncology practices urged CMS not to "reduce the size of the reimbursement reduction" or to phase in the adjustment over 2 to 3 years because the commenter believed that hospitals would use that time to "aggressively strong-arm independent community oncology practices to sell out to them."

Response: As stated earlier in this section, we are finalizing our proposal to pay ASP minus 22.5 percent for separately payable nonpass-through drugs (other than vaccines). In addition, we agree that it is not necessary to phase in the payment reduction and are implementing the full adjustment for CY 2018.

Comment: Commenters expressed concern about the challenges and costs of implementing acquisition cost billing. The commenters reported that hospital charge masters are not designed to bill drugs to one payer at a different rate than other payers. The commenters cited a survey response from hospitals that revealed acquisition cost billing would require investment in expensive software upgrades, obtaining a second charge master, or devising burdensome manual workarounds. One commenter stated that hospital cost reports already reflect the 340B acquisition cost based on expenses reported in the pharmacy cost center. The commenter further stated that these lower costs are already reflected in the drug CCR, which will likely be lower because the cost to acquire these drugs is lower. Thus, the commenter asserted, the OPPS ratesetting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition in the annual application of CCRs to pharmacy charges.

Response: We thank the commenters for their feedback and will take these comments into

consideration for future policymaking. We note that several State Medicaid programs require reporting of actual acquisition cost (AAC) for 340B drugs so the magnitude of the challenges to implement may be less than the commenter suggests.

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XVIII. Economic Analyses

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(2) Estimated Effects of OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7 of this final rule with comment period, we discuss our finalized policies to reduce the payment for nonpass-through, separately payable drugs purchased by certain 340B-participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from this payment policy in CY 2018. Specifically, in this final rule with comment period, for CY 2018, for hospitals paid under the OPPS (other than those that are excepted for CY 2018), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent instead of ASP+6 percent. For context, based on CY 2016 claims data, the total OPPS Part B drug payment is approximately $10.2 billion.

We recognize that it may be difficult to determine precisely what the impact on Medicare spending will be because OPPS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs covered under the 340B program is not publicly

available. Accordingly, for purposes of estimating the impact for this final rule with comment period, as we did in the CY 2018 OPPS/ASC proposed rule, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B Program were purchased at a discounted price under the 340B program. While we recognize that certain newly covered entities do not have access to 340B drug pricing for designated orphan drugs, we believe that our CY 2018 policy to except newly covered entity types such as rural SCHs, PPS-exempt cancer hospitals, and children's hospitals, largely mitigates the 340B drug spend attributable to orphan drugs and therefore does not dramatically affect our final estimate. In addition, for this final rule with comment period, we utilized the HRSA covered entity database to identify 340B participating hospitals and cross-checked these providers with the CY 2018 OPPS facility impact public use file to determine which 340B hospitals are paid under the OPPS. The HRSA covered entity database is available via the Internet at *https://340bopais.hrsa.gov/coveredentitysearch*. Using this database, we found 1,338 OPPS hospitals in the 340B program (compared to the 954 estimated for the proposed rule). Of these, 270 were rural SCHs, 47 were children's hospitals, and 3 were PPS-exempt cancer hospitals. We did not assume changes in the quantity of 340B purchased drugs provided by hospitals participating in the 340B program (thereby affecting unit volume) or changes in the number of hospitals participating in the 340B program that may occur due to the payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this final rule with comment period, we note that each hospital

has the ability to calculate how this policy will change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program or that is excepted from the policy to pay for drugs acquired under the 340B Program at ASP minus 22.5 percent in CY 2018 will know that its Medicare payments for drugs will be unaffected by this finalized policy; whereas each hospital participating in the 340B Program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, a hospital participating in the 340B Program is able to estimate the difference in payment that it will receive if Medicare pays ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using the list of participating 340B providers (derived from the HRSA database) and updated CY 2016 claims data available for this final rule with comment period for the applicable separately payable drugs and biologicals, excluding those on pass-through payment status and vaccines, billed by hospitals eligible to participate in the 340B Program, except for those hospital types that are excepted from this policy in CY 2018, we estimate that OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $1.6 billion under this finalized policy, which reflects an additional estimated reduction of $700 million over the proposed rule estimate of $900 million. If PPS-exempt cancer hospitals, children's hospitals, and rural SCHs had *not* been excluded from the reduced drug payment in CY 2018, drug payments to PPS-

exempt cancer hospitals would have been reduced by approximately $29 million, to children's hospitals by approximately $2 million, and to rural SCHs by approximately $199 million—this would have resulted in a total savings estimate of approximately $1.8 billion. Because we are implementing this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, we do not believe it is possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services. Furthermore, there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70352 through 70357).

In this final rule, we project that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018. The estimated impacts of this policy are displayed in Table

88 below. We note that the payment rates included in Addendum A and Addendum B of this final rule with comment period do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payments rates for non-drug items and services due to the corresponding increase in the conversion factor. In the proposed rule (82 FR 33712), we reminded commenters that this estimate could change in the final rule based on a number of factors, including other policies that are adopted in the final rule and the availability of updated data and/or method of assessing the impact in the final rule. We sought public comment on our estimate and stated that we were especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B Program.

We proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar would not be applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program.

In addition, we solicited public comment on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we sought public comment on whether and how the

offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. Finally, we sought public comment on whether the redistribution of savings associated with the proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

Comment: Several commenters stated that if the 340B drug payment policy was finalized, the funds should be redistributed across the OPPS, as has been the case for the application of budget neutrality in the past. One commenter supported CMS' proposal to implement the savings attributed to the 340B payment reduction in a budget neutral manner within the OPPS. Commenters noted that the budget neutrality requirement upon which CMS relied in the proposed rule at section 1833(t)(9)(B) of the Act has historically been interpreted by CMS as requiring budget neutrality within the OPPS. Commenters strongly urged CMS to follow its longstanding interpretation of section 1833(t)(9)(B) of the Act and offset the full amount of the aggregate 340B payment reduction through offsetting payment increases within the OPPS.

MedPAC reiterated its March 2016 recommendation that that payments be distributed in proportion to the amount of uncompensated care that hospitals provide, "to make sure that dollars in the uncompensated care pool actually go to the hospitals providing the most uncompensated care." MedPAC commented that the 340B Program is not well targeted to hospitals that provide high levels of uncompensated care and noted that 40 percent of 340B hospitals provide less than the median level of

uncompensated care. MedPAC stated that it believed that legislation would be needed to direct the savings to the uncompensated care pool because current law would require that the savings be retained within the OPPS to make it budget neutral. However, MedPAC encouraged CMS to request that Congress enact the legislation necessary to allow CMS to implement its recommendation. MedPAC further noted that legislation would also allow CMS to apply the policy to all separately payable drugs, including those that are separately payable as a result of their pass-through status.

Response: We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal to fully redistribute the savings associated with adoption of the alternative payment methodology for drugs acquired under the 340B Program within the OPPS to non-drug items and services. That is, we will redistribute $1.6 billion dollars in estimated lower payment for OPPS drugs by increasing the conversion factor for all OPPS non-drug items and services by 3.2 percent. We may revisit how the funds should be targeted in the future.

Comment: Some commenters challenged the accuracy of the $900 million estimate CMS calculated in the proposed rule. According to these commenters, their analysis of the proposal would have an estimated impact in the range of $1.2 billion to $1.65 billion. As a result, these commenters asserted that if the proposed payment reductions are applied in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, their analysis showed that payments for non-drug APCs would increase across hospitals by about 3.7 percent

(in contrast to CMS's estimate of 1.4 percent) based on the proposed rule data. Moreover, based on their analysis, the commenters believed the redistribution of the savings would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million—funding that they stated was intended to support the congressionally-mandated mission of 340B hospitals—not be redistributed to other hospitals that do not participate in the 340B Program.

Response: We stated in the proposed rule that the estimate of the 340B payment reductions would likely change in the final rule based on updated data, revised assumptions, and final policies. For this final rule with comment period, as discussed in detail earlier, we used updated CY 2016 claims data and an updated list of 340B eligible providers to calculate an estimated impact of $1.6 billion based on the final policy. As shown in Table 88 below this reflects a reduction of about $1.5 billion to urban hospitals and $86 million to rural hospitals. We are redistributing the savings from this payment reduction in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor. This increase to the conversion factor increases all OPPS non-drug payment rates to all providers under the OPPS by 3.2 percent. With respect to comments on the redistribution of the 340B savings to non-340B participating hospitals, we note that 340B hospitals will also receive the conversion factor increase.

Comment: In response to the comment solicitation on whether the savings generated by the reduced payment on 340B drugs should be used to increase payments for specific services paid under the OPPS or under Part B generally in CY 2018, commenters

generally objected to the notion that CMS has authority to redistribute savings outside of OPPS. One commenter stated that CMS did not provide any analysis or justification to support a reading that section 1833(t)(9)(B) of the Act establishes a budget neutrality concept for the Medicare Part B Trust Fund. Another commenter stated that CMS should not redistribute the savings gained by the 340B proposal based on Medicare DSH metrics (that is, insured low-income days) because such metrics are not well correlated with uncompensated care costs. This commenter also expressed concern regarding the suitability of using uncompensated care as a metric "to identify hospitals that provide the most help to needy patients because it includes bad debt as well as charity care." The commenter stated that bad debt is the amount that hospitals billed but did not collect, and therefore is not a measure of hospital assistance to the poor. Several commenters challenged the logic of reducing 340B payments to participating 340B hospitals, only to return the savings to the very same hospitals.

Response: We appreciate the feedback. Because the OPPS is a budget neutral payment system, historically CMS has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount. We have articulated the policy justification for reducing drug payment to ASP minus 22.5 percent for 340B-acquired drugs in section V.B.7. of this final rule with comment period and are redistributing the resulting dollars within the OPPS to maintain budget neutrality for CY 2018. Therefore, we are finalizing our proposal to redistribute the estimated reduction in payment for 340B-acquired

drugs and biologicals by increasing the conversion factor, and we are not targeting the savings to specific services paid under the OPPS or under Part B generally. We continue to be interested in exploring ways that funds from a subsequent proposal could be targeted in future years to hospitals that serve a high share of low-income or uninsured patients.

Comment: Many commenters noted that CMS' proposal to redistribute the savings that result from the 340B reduction in a budget neutral manner within the OPPS would increase beneficiary copayments on non-drug services. Accordingly, the commenters stated that most patients would not directly receive the benefit of the 340B copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs. The commenters stated the proposal will likely increase costs for uninsured patients because 340B hospitals provide a disproportionate amount of care to that population and participating 340B hospitals may no longer be able to provide "discounts to low-income patients" or other uncompensated care. One commenter suggested that CMS, with stakeholder input, develop an outpatient hospital charity care metric that could be used to redistribute the 340B savings based on the level of outpatient charity care provided by the hospital.

Response: We appreciate the stakeholders' concerns. We believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital. Further, to the extent that studies have found that 340B participating hospitals tend to use more high costs drugs, we believe

that this 340B payment policy helps address drug pricing in the hospital outpatient setting by lessening the incentive for unnecessary utilization of costly drugs. In addition, even though many beneficiaries have supplemental coverage, those plans make coinsurance payments on behalf of beneficiaries. Thus, to the extent this policy lessens the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans could decrease or otherwise reflect these lower costs in the future.

In summary, to maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increasing the payment rates by 3.2 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018.

(3) Estimated Effects of OPPS Changes on Hospitals

Table 88 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2018, we are paying CMHCs for partial hospitalization services under APC

5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2018 is 2.7 percent (82 FR 38177). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.6 percentage point for FY 2018 (which is also the MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38177 through 38178)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the OPD fee schedule increase factor of 1.35 percent. We are using the OPD fee schedule increase factor of 1.35 percent in the calculation of the CY 2018 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier

State wage index adjustment are incorporated in the CY 2018 estimates in Table 88.

To illustrate the impact of the CY 2018 changes, our analysis begins with a baseline simulation model that uses the CY 2017 relative payment weights, the FY 2017 final IPPS wage indexes that include reclassifications, and the final CY 2017 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2018 over CY 2017 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.35 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all payments for CY 2018 relative to all payments for CY 2017, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2018. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2018 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most

frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2017 and CY 2018 by various groups of hospitals, which CMS cannot forecast.

In CY 2016, we excluded all molecular pathology laboratory tests from our packaging policy, and in CY 2017, we expanded the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. For CY 2018, we sought public comments on whether laboratories (instead of hospitals) should be permitted to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act (and are granted ADLT status by CMS), that are ordered less than 14 days following the date of a hospital outpatient's discharge from the hospital outpatient department.

The laboratory date of service (DOS) issue is discussed in section X.F. of this final rule with comment period. Because there are currently no laboratory tests designated as ADLTs and because the payment rate for laboratory tests excluded from our packaging policy billed by a hospital would have been the applicable rate for the laboratory test under the CLFS, any aspect of this discussion that is finalized in this final rule with comment period will not result in a net costs or savings to the program. Accordingly, section X.F. of this final rule with comment period is not included in the impact table in the regulatory

impact analysis. Overall, we estimate that the rates for CY 2018 will increase Medicare OPPS payments by an estimated 1.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.5 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,878), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2016 hospital outpatient and CMHC claims data to model CY 2017 and CY 2018 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2017 or CY 2018 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,765), excluding the hold-harmless cancer and children's

hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 49 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience an increase of 0.1 percent, with the impact ranging from an increase of 0.1 percent to no change, depending on the number of beds. Rural hospitals will experience a decrease of 0.3 percent, with the impact ranging from a decrease of 0.2 percent to a decrease of 0.5 percent, depending on the number of beds. Major teaching hospitals will experience an increase of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2018 IPPS post-reclassification wage indexes; the rural adjustment; and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2017

conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2018, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2018 scaled weights and a CY 2017 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2017 and CY 2018. The FY 2018 wage policy results in modest redistributions.

There is a slight increase of less than 0.1 in Column 3 for the CY 2018 cancer hospital payment adjustment budget neutrality calculation because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2018 of 0.88, compared to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79869) payment-to-cost ratio target of 0.91. We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are

applying in section II.F. of this final rule with comment

Column 4: Effect of the Reduced Payment for 340B Drugs

Column 4 demonstrates the total payment effect of the finalized reduction in payment for drugs purchased under the 340B Program from ASP+6 percent to ASP minus 22.5 percent. This column includes both the reduced payment for 340B acquired drugs and the increase to the conversion factor for budget neutrality purposes, which increases payment for all non-drug services. For rural sole community hospitals, this column shows a 2.6 percent increase, reflecting a 0.0 percent increase for drugs (because these providers are exempt from these reductions) and a 3.2 percent increase for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 1.35 percent. Overall, these changes will increase payments to urban hospitals by 1.2 percent and to rural hospitals by 2.5 percent. Urban hospitals will receive an increase in line with the 1.3 percent overall increase for all facilities after the update is applied to the proposed budget neutrality adjustments. The increase for classes of rural hospitals is more variable with sole community hospitals receiving a 3.9 percent increase and other rural hospitals receiving an increase of 0.8 percent.

Column 6: All Changes for CY 2018

Column 6 depicts the full impact of the CY 2018 policies on each hospital group by including the effect of all of the changes for CY 2018 and comparing them

to all estimated payments in CY 2017. Column 6 shows the combined budget neutral effects of Columns 2 through 4; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2017 update (and assumed, for modeling purposes, to be the same number for CY 2018), we included 33 hospitals in our model because they had both CY 2016 claims data and recent cost report data. We estimate that the cumulative effect of all of the changes for CY 2018 will increase payments to all facilities by 1.4 percent for CY 2018. We modeled the independent effect of all of the changes in Column 6 using the final relative payment weights for CY 2017 and the final relative payment weights for CY 2018. We used the final conversion factor for CY 2017 of $75.001 and the final CY 2018 conversion factor of $78.636 discussed in section II.B. of this final rule with comment period.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) of 4.6 percent (1.04574) to increase individual costs on the CY 2016 claims, and we used the most recent overall CCR in the July 2017 Outpatient Provider-Specific File (OPSF) to estimate outlier

payments for CY 2017. Using the CY 2016 claims and a 4.6 percent charge inflation factor, we currently estimate that outlier payments for CY 2017, using a multiple threshold of 1.75 and a fixed-dollar threshold of $3,825 will be approximately 1.11 percent of total payments. The estimated current outlier payments of 1.11 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 9.4 percent (1.09357) and the CCRs in the July 2017 OPSF, with an adjustment of 0.985569, to reflect relative changes in cost and charge inflation between CY 2016 and CY 2018, to model the CY 2018 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,150. The charge inflation and CCR inflation factors are discussed in detail in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527).

Overall, we estimate that facilities will experience an increase of 1.4 percent under this final rule with comment period in CY 2018 relative to total spending in CY 2017. This projected increase (shown in Column 6) of Table 88 reflects the 1.35 percent OPD fee schedule increase factor, plus 0.2 percent for the change in the pass-through estimate between CY 2017 and CY 2018, minus a decrease of 0.11 percent for the difference in estimated outlier payments between CY 2017 (1.11 percent) and CY 2018 (1.0 percent). We estimate that the combined effect of all of the changes for CY 2018 will increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals will experience a 2.7 percent increase as a result of the combined effects of all of the changes for CY 2018.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects

of all changes will include a decrease of 0.9 percent for major teaching hospitals and an increase of 2.9 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.7 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.3 percent, proprietary hospitals will experience an increase of 4.5 percent, and governmental hospitals will experience no change.

* * *

Dated: October 26, 2017

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 30, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017-23932 Filed 11–1–17; 4:15 pm]

[83 Fed. Reg. 58,818 (Nov. 21, 2018)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–FC]

RIN 0938–AT30

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, we are updating the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by

removing the Communication about Pain questions; and retaining two measures that were proposed for removal, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure, in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program beginning with the FY 2021 program year.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2019.

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Table of Contents

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2019. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with

the OPPS and the ASC payment system. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this final rule with comment period, two quality reporting policies that impact inpatient hospitals are updated due to their time sensitivity. In the Hospital IQR Program, we are updating the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey, which are used to assess patients' experiences of care, effective with October 2019 discharges for the FY 2021 payment determination and subsequent years. This policy addresses public health concerns about opioid overprescribing through patient pain management questions that were recommended for removal in the President's Commission on Combating Drug Addiction and the Opioid Crisis report. In addition, we are finalizing that we will not publicly report any data collected from the Communication Abut Pain questions—a modification from what we proposed. We also are retaining two measures that we proposed for removal in the PCHQR Program beginning with the FY 2021 program year, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure. This policy impacts infection measurement and public reporting for PPS-exempt cancer hospitals and was deferred to this rule from the CY 2019 IPPS/LTCH PPS final rule published in August 2018.

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3. Summary of the Major Provisions

* * *

• *Application of 340B Drug Payment Policy to Nonexcepted Off-Campus Provider-Based Departments of a Hospital:* For CY 2019, as we proposed, we are paying the average sales price (ASP) minus 22.5 percent under the PFS for separately payable 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs) of a hospital. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

• *Payment Policy for Biosimilar Biological Products without Pass-Through Status That Are Acquired under the 340B Program:* For CY 2019, we are making payment for nonpass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar's own ASP rather than ASP minus 22.5 percent of the reference product's ASP.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals If Average Sales Price (ASP) Data Are Not Available*: For CY 2019, we are making payment for separately payable drugs and biologicals that do not have pass-through payment status and are not acquired under the 340B Program at wholesale acquisition cost (WAC)+3 percent instead of WAC+6 percent if ASP data are not available. If WAC data are not available for a drug or biological product, we are continuing our policy to pay for separately payable drugs and biologicals at 95 percent of the average wholesale price (AWP). Drugs and biologicals that are acquired under the 340B Program will continue to be

paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

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B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA)

(Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is

assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

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2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as

defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

• A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.

• A drug or biological for which a temporary HCPCS code has not been assigned.

• During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are

paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[57]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2019 OPPS/ASC proposed rule (83 FR 37122), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the

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[57] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.

Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2018.

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b. CY 2019 Payment Policy

In the CY 2019 OPPS/ASC proposed rule (83 FR 37122), for CY 2019, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to section V.A.7. of the proposed rule and this final rule with comment period for more information about how the payment rate for drugs acquired with a 340B discount was established.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for

the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II), the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS proposed rule, under section 1847A(c)(4), although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS proposed rule, we proposed that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act would utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used per our policy in effect as of CY 2018. For the OPPS, in the CY 2019 OPPS/ASC proposed rule (83 FR 37122), we also proposed to utilize a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We proposed that, if finalized, our proposal to

pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological. We stated in the proposed rule that for drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent) would continue to apply. We referred readers to the CY 2019 PFS proposed rule for additional background on this anticipated proposal.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also proposed that the budget neutral weight scalar not be applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the internet on the CMS website), which illustrate the final CY 2019 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2018, or WAC, AWP, or mean unit cost from CY 2017 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not the same as the actual January 2019 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2019

will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2018 (July 1, 2018 through September 30, 2018) will be used to set the payment rates that are released for the quarter beginning in January 2019 near the end of December 2018. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2018 are based on mean unit cost in the available CY 2017 claims data. If ASP information becomes available for payment for the quarter beginning in January 2019, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2018 ASP data) that do not have ASP information available for the quarter beginning in January 2019. As stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), these drugs and biologicals will then be paid based on mean unit cost data derived from CY 2017 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2019 payment purposes and are only illustrative of the CY 2019 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

Comment: A number of commenters supported CMS' proposal to continue to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent.

Response: We appreciate the commenters' support.

Comment: Several commenters supported the proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act, pursuant to CMS' authority under section 1833(t)(14)(A)(iii)(II) of the Act. These commenters recommended this as a first step to lowering drug costs for beneficiaries and the Medicare Program as well as removing the financial incentive associated with a specific prescribing choice. The commenters suggested modifying the add-on to be a flat fee.

Response: We appreciate the commenters' support. We proposed a fixed percentage, instead of a flat fee, in order to be consistent with other provisions in section 1847A of the Act that specify fixed add-on percentages of 6 percent (section 1847A(b) of the Act) or 3 percent (section 1847A(d)(3)(C) of the Act). A fixed percentage is also administratively simple to implement and administer, is predictable, and is easy for manufacturers, providers and the public to understand.

Comment: Many commenters opposed the proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act. Several commenters were concerned that paying less for new drugs may discourage the use of innovative drugs due to concerns about decreased payment, especially with the sequestration cuts decreasing the payment further. The commenters also were concerned that the proposal would only affect payment to the provider, and would not address pricing on the pharmaceutical manufacturer side. The commenters requested additional studies to analyze the appropriateness and accuracy of the 3 percent reduction, and encouraged

additional modifications to ASP reporting, such as requiring all Part B drug manufacturers to report pricing information and for all Part B drugs to be included in the ASP quarterly update file.

Response: We appreciate these comments. The implementation of these proposals will improve Medicare payment rates by better aligning payments with drug acquisition costs, which is of great importance to CMS because spending on Part B drugs has grown significantly. A WAC+3 percent add-on is more comparable to an ASP+6 percent add-on, as the WAC pricing does not reflect many of the discounts associated with ASP, such as rebates. The utilization of a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act is consistent with MedPAC's analysis and recommendations cited in its June 2017 Report to the Congress, and as discussed in the CY 2019 PFS proposed rule (83 FR 35854 through 35855). Overall, this policy still represents a net payment greater than the WAC. In addition, this policy decreases beneficiary cost-sharing for these drugs, which would help Medicare beneficiaries afford to pay for new drugs by reducing out-of-pocket expenses.

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c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for

CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same

manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP+6 percent of the reference product's ASP.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the current payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also believed this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

Comment: Many commenters supported CMS' proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. The commenters stated that this proposal would ensure fair access to biosimilar treatments.

Response: We appreciate the commenters' support. We believe this proposal appropriately reflects the resources and production costs that manufacturers incur, as well as more closely aligns with the hospitals' acquisition costs for these products.

Comment: Several commenters supported CMS' proposal to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenters stated that this proposal would continue to lower costs and improve access to treatments.

Response: We appreciate the commenters' support.

Comment: Some commenters recommended eliminating the proposal to continue the policy in place from CY 2018 to make all biosimilar biological

products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenters believed this policy could potentially encourage inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment.

Response: We are not convinced that making all biosimilar biological products eligible for pass-through payment will lead to inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment. Eligibility for pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals.

After consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also are finalizing our proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the payment policy for therapeutic radiopharmaceuticals

that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2019. Therefore, we proposed for CY 2019 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2017 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with

comment period (74 FR 60524). The proposed CY 2019 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Comment: Commenters supported continuation of the policy to pay ASP+6 percent for therapeutic radiopharmaceuticals, if available, and to base payment on the mean unit cost derived from hospital claims data when not available. The commenters also requested that CMS examine ways to compensate hospitals for their documented higher overhead and handling costs associated with radiopharmaceuticals.

Response: We appreciate the commenters' support. However, as we stated earlier in section V.B.1.c. of this final rule with comment period in response to a similar request for additional radiopharmaceutical payment and as previously stated in the CY 2018 OPPS final rule with comment period (82 FR 59352), we continue to believe that a single payment is appropriate for radiopharmaceuticals with pass-through payment status in CY 2019 and that the payment rate of ASP+6 percent is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy. Payment for the radiopharmaceutical and radiopharmaceutical processing services is made through the single ASP-based payment. We refer readers to the CMS guidance document available via the internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Archives.html* for details on submission of ASP data for therapeutic radiopharmaceuticals.

Comment: One commenter asked CMS to clarify the payment rate reported for APC 1675, P32 Na phosphate (HCPCS code A9563), which is based on geometric mean unit cost. The commenter stated that, in the proposed rule, the payment rate for HCPCS code A9563 was reported as $256.00, but the mean unit cost for the radiopharmaceutical as reported in data files accompanying the proposed rule was $519.21.

Response: We thank the commenter for bringing this reporting error to our attention. We are providing a corrected payment rate for APC 1675, P32 Na phosphate (HCPCS code A9563) in Addenda A and B of this final rule with comment period (which is available via the internet on the CMS website).

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2017 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2019 final payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

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7. CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the Medicare Part B drug payment methodology for 340B

hospitals. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We believed that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP)+6 percent to ASP minus 22.5 percent. Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not included in this 340B policy change because they are paid under section 1834(g) of the Act. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs on pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37125), another topic that has been brought to our attention since we finalized the

payment adjustment for 340B-acquired drugs in the CY 2018 OPPS/ASC final rule with comment period is whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. We did not receive public comments on this topic in response to the CY 2018 OPPS/ASC proposed rule. However, we have since heard from stakeholders that there has been some confusion about this issue. We clarified in the CY 2019 proposed rule that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent and AWP-priced drugs have a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

Furthermore, data limitations previously inhibited our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and

non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the CY 2018 proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program. As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier "JG", effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals are required to report informational modifier

"TB" for 340B-acquired drugs, and continue to be paid ASP+6 percent.

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifier "JG".

In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we calculate payment for 340B-acquired biosimilars (that is, we proposed to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP). More information on our revised policy for the payment of biosimilars acquired through the 340B Program is available in section V.B.2.c. of this final rule. We proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator "K"), other than vaccines and drugs on pass-through payment status, that meet the definition of "covered outpatient drug" as defined in section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the CY 2018 proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the

340B Program. As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier "JG", effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals are required to report informational modifier "TB" for 340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifier "JG". In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we calculate payment for 340B-acquired biosimilars (that is, we proposed to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP). More information on our revised policy for the payment of biosimilars acquired through the 340B Program is available in section V.B.2.c. of this final rule. We proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator "K"), other than vaccines and drugs on pass-

through payment status, that meet the definition of "covered outpatient drug" as defined in section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator "L' or "M") and drugs with OPPS transitional pass-through payment status (assigned status indicator "G"). As discussed in section V.B.2.c. of the proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. We also proposed that Medicare would continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

As stated earlier, to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier "JG", effective January 1, 2018. For CY 2019, we proposed that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS, or excepted from the 340B drug payment policy for CY 2018, continue to be required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. We also proposed for CY 2019 that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment. We proposed that these hospitals be required to report informational modifier "TB" for 340B-acquired drugs, and continue to be paid ASP+6 percent.

Comment: One commenter supported the proposal to continue to pay for separately payable drugs and

biologicals obtained through the 340B program at ASP minus 22.5 percent. The commenter believed the payment rate of ASP minus 22.5 percent will help CMS address the large amount of growth in the 340B Program by increasing oversight and promoting the integrity of the program.

Another commenter, MedPAC, also supported the proposal. MedPAC believed a lower payment rate allows beneficiaries to share in the savings from the 340B Program, better targets resources to hospitals providing the most uncompensated care, and still allows 340B hospitals to make a profit off the drugs obtained through the program. MedPAC preferred that the payment rate be ASP+6 percent minus a 10 percent discount with the savings assigned to a Medicare-funded uncompensated care pool, but noted that this policy requires Congressional action.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed the CY 2019 proposal to continue to pay for separately payable drugs and biologicals obtained through the 340B Program at ASP minus 22.5 percent. Many commenters stated that the new payment rate has hurt hospitals financially and has hurt efforts by hospitals to provide safety-net care to their patients. The commenters were also concerned about the same service costing more at non-340B hospitals than at hospitals enrolled in the 340B Program because drugs furnished at a non-340B hospital would be paid at ASP+6 percent while drugs furnished at a 340B hospital would be paid at ASP minus 22.5 percent. One commenter whose hospital provides cancer treatment stated the reductions in 340B payment mean the hospital cannot provide the broader cancer care options available at non-340B hospitals. Commenters

also stated that reducing payment for drugs acquired through the 340B Program does not help reduce high drug costs. Many commenters asserted, as they have previously done, that CMS does not have the legal authority to implement payment reductions for drugs and biologicals obtained through the 340B Program. The commenters requested that CMS end its policy of paying for drugs obtained through the 340B program at ASP minus 22.5 percent. Instead, the commenters suggested that CMS go back to the payment policy that was in place before CY 2018 where drugs acquired through the 340B Program were paid at ASP+6 percent.

Response: The commenters stated that the payment rate of ASP minus 22.5 percent for drugs and biologicals has caused financial harm to hospitals and has caused problems for hospitals to provide safety-net care to their patients. We noted in the CY 2018 final rule with comment period (82 FR 59358 through 59359) that the OPPS payment rate of ASP+6 percent at that time significantly exceeded the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout that section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive.

Regarding the concerns of the commenters that drugs and biologicals and services where drugs and biologicals are packaged into the cost of the service would cost more at hospitals that do not participate in the 340B Program as compared to hospitals participating in the 340B Program, any differential in these costs is a feature of the 340B Program rather

than Medicare payment policy. In fact, one of the objectives of our payment policy for drugs and biologicals acquired through the 340B Program is to lower costs for Medicare beneficiaries, and we believe it is appropriate that hospitals participating in the 340B Program pass the cost savings they receive to their beneficiaries.

Finally, regarding the commenters' assertion that CMS lacks the legal authority to continue requiring payment reductions for drugs and biologicals obtained through the 340B Program, we refer these commenters to our detailed response regarding our statutory authority to require payment reductions for drugs and biologicals obtained through the 340B Program in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59359 through 59364).

After consideration of the public comments we received, we are finalizing our proposals without modification. For CY 2019, we are continuing the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of this final rule with comment period. We refer readers to the CY 2018 final rule with comment period (82 FR 59369 through 59370) for more detail on the policies implemented in CY 2018 for drugs acquired through the 340B Program.

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C. Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

1. Historical Perspective

a. Section 603 of the Bipartisan Budget Act of 2015

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an "off-campus outpatient department of a provider," which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an "off-campus outpatient provider-based department" or an "off-campus PBD." For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

b. Applicable Payment System

As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143 through 37144), to implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the Medicare PFS as the "applicable payment system" that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. As we discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79718) and reiterated in the CY 2018 PFS final rule with comment period (82 FR 53028), payment for Medicare Part B drugs that would be separately payable under the OPPS (assigned a status indicator of "K"), but are not payable under the OPPS because they are furnished by nonexcepted off-campus PBDs, is made in accordance with section 1847A of the Act (generally, at a rate of ASP+6 percent), consistent with Part B drug payment policy for items or services furnished in the physician office (nonfacility) setting. We did not propose or make an adjustment to payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, but indicated we may consider doing so through future notice-and-comment rulemaking.

In the interim final rule with comment period that accompanied the CY 2017 OPPS/ASC final rule with comment period, we established payment policies under the Medicare PFS for nonexcepted items and services furnished by a nonexcepted off-campus PBD on or after January 1, 2017. In accordance with sections 1848(b) and (c) of the Act, Medicare PFS payment is based on the relative value of the resources

involved in furnishing particular services (81 FR 79790). Resource-based relative values are established for each item and service (described by a HCPCS code(s)) based on the work (time and intensity), practice expense (such as clinical staff, supplies and equipment, office rent, and overhead), and malpractice expense required to furnish the typical case of the service. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services that are valued under the PFS, we establish two different PFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the PFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). Consistent with the long-established policy under the PFS to make payment to the billing practitioner at the facility rate when Medicare makes a corresponding payment to the facility (under the OPPS, for instance) for the same service, physicians and nonphysician practitioners furnishing services in nonexcepted PBDs continue to report their services on a professional claim form and are paid for their services at the PFS facility rate.

Similarly, there are many (mostly diagnostic) services paid under the PFS that have two distinct portions of the service: A technical component (TC) and a professional component (PC). These components can be furnished independently in time or by different suppliers, or they may be furnished and billed together as a "global" service (82 FR 52981). Payment for these services can also be made under a combination of payment systems; for example, under the PFS for the

professional component and the OPPS for the facility portion. For instance, for a diagnostic CT scan, the technical component relates to the portion of the service during which the image is captured and might be furnished in an office or HOPD setting, and the professional component relates to the interpretation and report by a radiologist.

In the CY 2017 interim final rule with comment period, we stated that we continue to believe that it is operationally infeasible for nonexcepted off-campus PBDs to bill directly under the PFS for the subset of PFS services for which there is a separately valued technical component (81 FR 79721). In addition, we explained that we believe hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. We stated that we therefore believe it is necessary to establish a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS that is specific to one site of service (the off-campus PBD of a hospital) with the packaging (bundling) rules that are significantly different from current PFS rules (81 FR 79721).

In continuing to implement the requirements of sections 1833(t)(1)(B) and (t)(21) of the Act, we recognize that there is no established mechanism for allowing hospitals to report and bill under the PFS for the portion of resources incurred in furnishing the full range of nonexcepted items and services. This is because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services generally furnish a broader range of services than other provider

or supplier types for which there is a separately valued technical component under the PFS. As such, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting.

Nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line (modifier "PN") to indicate that an item or service is a nonexcepted item or service. For a detailed discussion of the current PFS relativity adjuster related to payments under section 603 of Public Law 114–74, we refer readers to the CY

2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637), the CY 2018 PFS final rule with comment period (82 FR 53019 through 53025), and the CY 2019 PFS proposed rule.

c. Section 340B of the Public Health Service Act

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37144 through 37145), the 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33632 through 33635), we proposed changes to the payment methodology under the OPPS for separately payable drugs and biologicals acquired under the 340B Program. We stated that these changes would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs that are purchased under the 340B Program to Medicare beneficiaries. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period, we finalized our proposal that separately payable, covered outpatient drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program will be paid ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a

hospital paid under the OPPS that is not excepted from the payment adjustment. CAHs are not subject to this 340B policy change because they are paid under section 1834(g) of the Act. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the alternative payment methodology for 340B-acquired drugs and biologicals. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or to vaccines, which are excluded from the 340B Program.

2. Proposal and Final Policy To Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79716), prior to the implementation of the payment adjustment under the OPPS for drugs and biologicals acquired under the 340B program, separately payable drugs and biologicals were paid the same rate at both excepted and nonexcepted off-campus departments of a hospital. The policy we finalized in the CY 2018 OPPS/ASC final rule with comment period, in which we adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from ASP+6 percent to ASP minus 22.5 percent, applies to separately payable drugs and biologicals paid under the OPPS (81 FR 59353 through 59369). Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, in accordance with our policy in effect as of CY 2018, nonexcepted items and services

furnished by nonexcepted off-campus PBDs are no longer covered outpatient department services and, therefore, are not payable under the OPPS. This means that nonexcepted off-campus PBDs are not subject to the payment changes finalized in the CY 2018 OPPS/ASC final rule with comment period that apply to hospitals and PBDs paid under the OPPS. Because the separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off-campus PBDs are no longer covered outpatient department services, as of CY 2018, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings—typically at ASP+6 percent—regardless of whether they are acquired under the 340B Program.

The current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In establishing these policies in prior rulemaking, we pointed out that the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the PFS localities, which reflect cost

differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP+6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a per-day cost exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in section V.A.1. of the CY 2019 OPPS/ASC proposed rule, section 1847A of the Act establishes the ASP methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC, and the AWP (82 FR 59337). As noted in section V.B.2.b. of the CY 2019 OPPS/ASC proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section

1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350). Consequently, in the case of services furnished in a hospital outpatient department, Medicare pays ASP+6 percent for separately payable Part B drugs and biologicals unless those drugs or biologicals are acquired under the 340B Program, in which case they are paid at ASP minus 22.5 percent. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59343 through 59371).

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37146), as a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately payable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term "applicable payment system," we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined

under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59354), several recent studies and reports on Medicare Part B payments for 340B-acquired drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost. When we initially developed the policy for nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid, both in the OPPS and in other Part B settings, such as physician offices, through similar methodologies under section 1847A/1842(o) of the Act. For drugs and biologicals that are packaged in the OPPS, we adopted similar packaging payment policies for purposes of making the site-specific payment under the PFS for nonexcepted off-campus PBDs. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted PBD or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates

and could result in significant perverse incentives for hospitals to acquire drugs and biologicals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. In light of the significant drug payment differences between excepted and nonexcepted off-campus PBDs, in combination with the potential eligibility for discounts, which result in reduced costs under the 340B Program for both kinds of departments, our current payment policy could undermine the validity of the use of the OPPS payment structure in nonexcepted off-campus PBDs. In order to avoid such perverse incentives and the potential resulting distortions in drug payment, in the CY 2019 OPPS/ASC proposed rule (83 FR 37146), we proposed, pursuant to our authority at section 1833(t)(21)(C) of the Act, to identify the PFS as the "applicable payment system" for 340B-acquired drugs and biologicals and, accordingly, to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs. We stated in the proposed rule that we believe this proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs, which we believe is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPPS and PBDs paid under the PFS using the PFS relativity adjuster.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59367 through 59368), we discussed

public comments that we received that noted that the alternative payment methodology for 340B-acquired drugs and biologicals did not apply to nonexcepted off-campus PBDs of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of Public Law 114–74. Commenters recommended that, if CMS adopted a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program (82 FR 59367). While we did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, we indicated that we would consider adopting such a policy in future rulemaking.

We agree with commenters that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments, excepted off-campus PBDs versus nonexcepted off-campus PBDs, creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37145), we proposed changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program. Specifically, for CY 2019 and

subsequent years, we proposed to pay under the PFS the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital. Furthermore, we proposed to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment (83 FR 37145). We stated that we believe that our proposed payment policy would better reflect the resources and acquisition costs that nonexcepted off-campus PBDs incur for these drugs and biologicals.

Comment: Some commenters, including organizations representing physician oncology practices, orthopedic surgeons, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, physician organizations, and health insurers, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, preserve patient access to community-based care, and address the significant incongruity between the payment amounts for 340B-acquired drugs, depending upon the setting in which they are furnished. One of these commenters, a pharmaceutical company, stated that the 340B Program has grown beyond its original intent and needs to be refocused to better meet the needs of vulnerable patients. The commenter noted that there is an incentive to inappropriately shift administration of drugs from excepted to nonexcepted off-campus PBDs for the purpose of securing higher payment. In addition, the commenter urged HHS to adopt policies "that prevent the unjustified expansion

of the 340B program to unintended populations through contract pharmacies, child sites, and individuals who Congress did not intend to be considered 340B patients."

A few commenters, including organizations representing community oncology practices, stated that the opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices. Furthermore, one of these commenters asserted that, when these facilities purchased by 340B-participating entities become off-campus PBDs, they also become eligible for 340B Program discounts, thus "further fueling the program's staggering growth." These commenters cited a report that states that, over the last decade, 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for the 340B Program. Accordingly, these commenters believe that the growth of Part B drug spending in recent years has been disproportionately driven by higher payments in the hospital outpatient setting. Another commenter asserted that the current situation creates two undesirable incentives. First, it creates an incentive for physicians to join a hospital to furnish the same types of services that could have been furnished in the physician office setting, thereby increasing costs to the Medicare program, Medicare beneficiaries, and taxpayers without any associated increase in access to care for Medicare beneficiaries, particularly low-income beneficiaries. Second, it encourages hospitals to move services off the hospital campus for financial incentives.

Some commenters urged CMS and HRSA to work with Congress to reform the 340B Program. One commenter recommended that CMS gather additional data to better understand 340B Program acquisition costs and the impact of payment reductions on 340B Program providers. In addition, a few commenters recommended that CMS revise the definition of "patient" to reflect the program's original intent.

Response: We thank commenters for their support and recommendations. We agree with the commenters that the difference in the payment amounts for 340B-acquired drugs furnished by different types of hospital outpatient departments, excepted off-campus PBDs versus nonexcepted off-campus PBDs, creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, we continue to believe that our proposed policy will better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs in nonexcepted off-campus PBDs of a hospital.

As we previously stated, CMS does not administer the 340B Program. Accordingly, comments related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: One commenter, who cited studies conducted by the GAO, OIG, and MedPAC, suggested

that CMS make additional downward adjustments to drug payments under the 340B Program in future years because the 22.5 percent payment reduction "was conservative" and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent. The commenter asserted that 22.5 percent reflects the average minimum discount that 340B hospitals receive for drugs acquired under the program, and that discounts across all 340B providers average 33.6 percent of ASP.

Response: We thank the commenter for this feedback. We will continue to analyze the data on these drugs for future rulemaking. As we mentioned in the CY 2019 OPPS/ASC proposed rule, we share the commenter's concern that current Medicare payments for drugs acquired by nonexcepted off-campus PBDs are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We also continue to believe that Medicare beneficiaries should be able to benefit from the significant discounts hospitals receive on 340B-acquired drugs through reduced copayments.

Comment: One commenter, an organization representing children's hospitals, supported the proposal to except children's hospitals from the proposed payment policy for drugs purchased under the 340B Program. However, the commenter asserted that children's hospitals are undercompensated by government programs, and that a recent report found that the overall Medicare margin for all hospitals is negative. Furthermore, the commenter stated that, while self-governing children's hospitals are excepted from the payment policy, children's hospitals within academic medical centers or health care systems remain subject to this policy, which will curtail the

ability of such children's hospitals to care for needy children. The commenter urged CMS not to apply this policy to children's hospitals within academic medical centers or health care systems.

Response: We thank the commenter for its support and feedback. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59366), because of how children's hospitals are paid under the OPPS, we acknowledged that the 340B drug payment policy may not result in reduced payments for these hospitals in the aggregate. While the payment policy we are establishing in this final rule with comment period applies to nonexcepted departments of a hospital that are paid under the PFS rather than the OPPS, we believe that adopting an analogous policy, regardless of status, is prudent so that a generally excepted hospital receives payment for drugs in the same manner, regardless of the status (excepted or nonexcepted) of each PBD of the hospital.

In addition, it is unclear from the comment whether the referenced children's hospitals "within academic medical centers or health care systems" are enrolled in the Medicare program as children's hospitals or whether they are simply a department of an enrolled hospital provider. However, any separately enrolled children's hospital that is paid as such is exempt from the 340B-acquired drug payment reduction, while children's units that are not separately enrolled would not be exempt from the 340-acquired drug payment policy.

Comment: A few commenters, including organizations representing sole community hospitals, supported the proposal to extend the exception for rural sole community hospitals from the proposed 340B Program payment adjustment. However, these

commenters remained concerned that other vulnerable hospitals continue to be subject to the 340B Program payment reduction. Accordingly, these commenters recommended that CMS exempt urban sole community hospitals, Medicare-dependent hospitals, and hospitals with rural referral center status from the payment adjustment. In addition, rural hospitals recommended that rural providers be permanently excepted from this policy.

Response: We share commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. Consequently, for CY 2019, we are excluding rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. However, we do not believe that a payment exemption for nonexcepted off-campus departments of urban SCHs is necessary because these hospitals are not exempted from the 340B payment policy for hospital departments paid under the OPPS. Nonetheless, we will continue to analyze the data for these hospitals to determine whether urban SCHs should be exempt from this payment policy, as well as whether permanent exemption for rural SCHs is warranted in future rulemaking.

With respect to rural referral centers, in the CY 2018 OPPS/ASC final rule with comment period, we

noted that there is no special payment designation for rural referral centers under the OPPS. By definition, rural referral centers must have at least 275 beds and therefore are larger relative to rural sole community hospitals. In addition, rural referral centers are not subject to a distance requirement from other hospitals. Accordingly, rural referral centers are neither as small (in terms of bed size) or as isolated (in terms of proximity to other hospitals) as rural SCHs, nor are they generally eligible for special payment status under the OPPS, and we do not believe that a payment exemption from this policy for these centers is warranted.

Furthermore, as stated earlier in this section, we believe that we should adopt an analogous payment policy across hospital settings, regardless of the status of each PBD. Because we did not exempt grandfathered off-campus PBDs with MDH classification from the 340B payment adjustment in CY 2018, we do not believe that nonexcepted off-campus PBDs with Medicare-dependent hospital status should be exempted at this time. Therefore, for CY 2019, Medicare-dependent hospitals will not be exempt from this payment policy.

For CY 2019, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals will be excepted from the alternative payment methodology for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs, and therefore will be required to bill under the PFS using the institutional claim form and report the informational modifier "TB" for 340B-acquired drugs and biologicals. These providers will continue to be paid ASP+6 percent for 340B-acquired drugs and biologicals under the PFS. In addition, as we stated in

the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or to vaccines, which are excluded from the 340B Program.

We note that this policy does not alter covered entities' access to the 340B Program. The expansion of the alternative 340B drug payment methodology solely changes Medicare payment for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program. We may revisit our policy regarding exceptions to the 340B drug payment reduction in the CY 2020 OPPS/ASC rulemaking.

Comment: In its comment, MedPAC reiterated recommendations included in its March 2016 Report to Congress. In this report, MedPAC recommended that payment rates for all separately payable drugs provided in a 340B hospital be reduced by 10 percent of the current payment rate of ASP+6 percent (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to Congress that savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged

the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such a recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status. Accordingly, MedPAC recognized that CMS does not have the legal authority to implement its March 2016 recommendation and shares CMS' concern that the lack of site-neutral payments may cause a shift in administration of nonpass-through separately payable drugs to nonexcepted off-campus PBDs. Additionally, MedPAC stated that CMS should ensure that payment for 340B-acquired drugs is equal across settings.

Response: We thank MedPAC for its support and feedback. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59364 through 59365), we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B-participating hospitals.

We note that we responded to a similar public comment in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59364 through 59365) and refer readers to a summary of that comment and our response.

Comment: Many commenters stated that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs acquired in off-campus PBDs, and contended that the expansion of the 340B payment policy at nonexcepted

off-campus PBDs would "effectively eviscerate" the 340B Program. These commenters further noted that extending the Medicare payment cuts to nonexcepted off-campus PBDs would greatly undermine 340B hospitals' ability to continue programs designed to improve access to services.

One commenter, an organization representing over 1,300 public and nonprofit providers enrolled in the 340B Program, argued that since the 340B payment policy took effect in January 2018, many hospitals have experienced financial and operational challenges, including staff reductions, fewer free or discounted drugs for patients, clinic and pharmacy closures, and reductions in services provided. The commenter opposed the 340B payment proposal for a number of reasons, primarily because the commenter believed that the current OPPS 340B payment rate harms hospitals' ability to treat low-income patients and the proposals to continue and expand the cuts would worsen the impact. Furthermore, the commenter argued that CMS' proposed payment reduction does not reduce patient costs or Medicare spending or address "skyrocketing drug prices"; CMS' payment reduction violates the 340B statute; CMS' payment reduction violates the Medicare statute; and CMS' payment reduction relies on a "faulty premise that fails to recognize that 340B hospitals serve patients with more expensive medical needs." The commenter further asserted that Congress, as well as "one-hundred percent of hospitals," have expressed concern about the payment reduction's impact on 340B providers' ability to serve their patients.

Many additional commenters, including some hospital associations, contended that CMS does not have the legal authority to apply the OPPS Medicare

payment rate to nonexcepted off-campus PBDs in 340B-participating hospitals because section 1833(t)(21)(C) of the Act does not authorize CMS to pay at a rate that is less than the rate paid under the selected "applicable payment system." Specifically, a few commenters asserted that payment for these drugs and biologicals is determined pursuant to the rules of section 1842(o)(1)(C) of the Act, which mandates that payment is to be made for these drugs and biologicals when furnished by nonexcepted off-campus PBDs pursuant to the rules of section 1847A of the Act.

Response: We do not believe that the proposed payment policy violates section 340B of the Public Health Service Act or the Social Security Act. There is no requirement in the Public Health Service Act that drugs or biologicals acquired under the 340B Program generate a profit margin for hospitals through Medicare payments, and there is no requirement in any part of section 1833(t) of the Social Security Act to pay a particular minimum rate for a hospital enrolled in the 340B Program Further, we disagree with the commenter's assertion that CMS' payment reduction does not reduce patient costs or Medicare spending. Based on our proposed adjustment for CY 2019, we estimated that the Medicare Program and beneficiaries would save approximately $49 million under the PFS.

We also disagree with commenters who believe that the OPPS payment rate for 340B-acquired drugs will "effectively eviscerate" the 340B Program as well as the implication that extending the same rate that applies to 340B-acquired drugs and biologicals furnished by hospital departments under the OPPS to nonexcepted off-campus PBDs will perpetuate that

concern. The findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. Indeed, in some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). As stated in the CY 2018 final rule with comment period, we believe that ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs, and that even with the reduced payments, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program. We also have noted that 340B Program participation does not appear to be well aligned with the provision of uncompensated care, as some commenters suggested (82 FR 59359).

Payment under the "applicable payment system" pursuant to section 1833(t)(21)(C) of the Act is made under the PFS for most services, including for the many drugs that are packaged under the OPPS, using a PFS relativity adjuster that is applied to the OPPS payment rate. As such, the PFS payment for nonexcepted items and services in nonexcepted off-campus PBDs is made on a prospective payment basis, and we are therefore not required to make payment under section 1847A/1842(o) of the Act for those packaged drugs, many of which would be separately payable under the PFS. Further, as we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37145), the current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In

establishing these policies in prior rulemaking, we pointed out that the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the PFS localities, which reflect cost differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

Since we have adopted the payment adjustment under the OPPS for 340B-acquired separately payable drugs, we have become concerned that there would be a perverse incentive for hospitals to circumvent the OPPS payment adjustment by furnishing 340B-acquired drugs in nonexcepted off-campus PBDs where Medicare currently makes payment for those drugs at ASP+6 percent. To avoid this payment incongruity and perverse incentive, we proposed to designate the PFS as the "applicable payment system" for 340B-acquired separately payable drugs furnished in nonexcepted off-campus PBDs, and to make payment at the OPPS-comparable rate.

Comment: A few commenters asserted that, while CMS estimated that the payment change would result in a payment cut of $48.5 million in CY 2019, CMS provided no data to support this estimate and failed to

provide sufficient access to data, its methodology, or its analysis to allow the public to assess and replicate the proposed CY 2019 340B payment policy. One commenter recommended that CMS delay extension of the 340B payment policy until more information is available related to the impact on Medicare beneficiaries.

Many commenters opposed reducing payments to hospitals for 340B drugs in a nonbudget-neutral manner and instead suggested that such policy be implemented in a budget neutral manner as was implemented in the CY 2018 OPPS/ASC final rule with comment period. In addition, some commenters recommended that CMS annually calculate a budget neutral adjustment for the 340B policy, as the approach is consistent with other budget neutral policies included in the OPPS.

Response: We thank the commenters for their input. We disagree that this policy should be implemented in a budget neutral manner because the payments made to nonexcepted off-campus departments of a hospital are not paid under the OPPS. As we stated in the CY 2019 OPPS/ASC proposed rule, to develop an estimated impact of this proposal, we analyzed the CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed rule. Based on the most recent claims data from CY 2017 reporting, we found 117 unique nonexcepted off-campus PBDs associated with 340B hospitals that billed for status indicator "K" drugs. Their "K" billing represents approximately $182.5 million in Medicare payments based on a payment rate of ASP+6 percent. Based on our proposed adjustment, for CY 2019, we estimated that the Medicare Program and beneficiaries would save approximately $49 million

under the PFS. Regarding budget neutrality requirements, we note that when we initially developed the payment policy for nonexcepted items and services furnished by nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid at the same rates specified under section 1847A/1842(o) of the Act (generally, ASP+6) when furnished in the HOPD and in other outpatient settings, such as physician offices. When we initially established the ASP methodology under section 1847A/1842(o) of the Act as the "applicable payment system" for separately payable drugs under section 1833(t)(21)(C) of the Act, there was no applicable budget neutrality requirement. For the proposed change in CY 2019 to establish the PFS as the applicable payment system for separately payable 340–B-acquired drugs furnished by nonexcepted off-campus PBDs, we believe the site-specific PFS payment for these drugs and biologicals represents new utilization under the PFS and would, consequently, not be subject to the PFS budget neutrality requirements under 1848(c) of the Act for CY 2019. We will consider any applicable budget neutrality requirements regarding the site-specific payment under the PFS for future rulemaking.

Comment: Numerous commenters argued that reducing payments for 340B-acquired drugs could encourage hospitals to selectively purchase certain drugs at higher prices outside of the 340B Program to maximize revenue. One of these commenters recommended the implementation of alternate reimbursement methodologies for 340B-purchased drugs, such as a 6 percent add-on payment to the product-specific estimated 340B cost, in order to discourage hospitals from selectively purchasing some drugs outside of the 340B Program (resulting in ASP

minus 16.5 percent after taking application of the add-on payment into account).

Response: While participation in the 340B Program has always been voluntary and hospitals have always had the ability to choose to purchase drugs outside the 340B Program, we do not see the relevance of these points to our proposed policy. That is, the policy we proposed with respect to payment for 340B-acquired drugs in nonexcepted departments for CY 2019 simply aligns with the policy already established for 340B-acquired drugs under the OPPS for CY 2018. In addition, as we explained in CY 2018 OPPS rulemaking, the payment rate of ASP minus 22.5 percent is better aligned with the average resources to acquire a 340B drug, and therefore, we do not believe that a higher payment rate for 340B-acquired drugs in nonexcepted departments is warranted.

We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal, without modification, to make payment for separately payable 340B-acquired drugs furnished by nonexcepted off-campus departments of a hospital under the PFS, and to establish the payment rate for those drugs at ASP minus 22.5 percent. This policy is expected to lower the cost of drugs and biologicals for Medicare beneficiaries and ensure that they benefit from the discounts provided through the program, and to do so more equitably across HOPD settings.

In summary, for CY 2019, in accordance with section 1833(t)(21)(C) of the Act and our established 340B payment methodology as described in the CY 2018 OPPS/ASC final rule with comment period, separately payable Part B drugs and biologicals (assigned status indicator "K"), other than vaccines

and drugs with pass-through payment status, that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at a rate of ASP minus 22.5 percent when billed by a hospital that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator "L" or "M") and drugs and biologicals with transitional pass-through payment status (assigned status indicator "G"). Medicare will continue to pay for drugs and biologicals that are not purchased with a 340B Program discount at ASP+6 percent.

To effectuate the payment adjustment for 340B-acquired drugs and biologicals, CMS implemented modifier "JG", effective January 1, 2018. Hospitals paid under the OPPS (other than a type of hospital excluded from the OPPS or excepted from the 340B drug payment policy for CY 2019) and, beginning January 1, 2019, nonexcepted off-campus PBDs of a hospital paid under the PFS, are required to report modifier "JG" on the same claim line as the drug or biological HCPCS code to identify a 340B-acquired drug or biological. For CY 2019, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier "TB" for 340B-acquired drugs and biologicals, and will continue to be paid ASP+6 percent.

* * *

As noted in sections V.B.7. and X.C.2. of this final rule with comment period, we are finalizing our proposal for CY 2019 to pay for separately payable drugs and biological products that do not have pass-

through payment status and are not acquired under the 340B program at WAC+3 percent instead of WAC+6 percent, if ASP data are unavailable for payment purposes. If WAC data are not available for a drug or biological product, we will continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. Drugs and biologicals that are acquired under the 340B Program will continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

* * *

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

* * *

c. Estimated Effects of Finalized Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of Hospitals

In section X.C. of this final rule with comment period, we discuss the proposal we are finalizing to pay average sales price (ASP) minus 22.5 percent under the PFS for separately payable 340B-acquired drugs furnished by nonexcepted, off-campus PBDs beginning in CY 2019. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

To develop an estimated impact of this finalized proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 OPPS. We then flagged all claim lines that contained modifier "PN" because the presence of this modifier indicates

that such claims were billed for services furnished by a nonexcepted off-campus department of a hospital paid under the PFS. We further subset this population by identifying 340B hospitals that billed for status indicator "K" drugs or biologicals (that is, nonpass-through, separately payable drugs) because such drugs may have been subject to the 340B discount. We found 117 unique nonexcepted off-campus PBDs associated with 340B hospitals billed for status indicator "K" drugs. Their "K" billing represents approximately $183 million in Medicare payments (including beneficiary copayments) based on a payment rate of ASP+6 percent. Based on our adjustment, for CY 2019, we estimate that the Medicare Program and beneficiaries will save approximately $49.1 million, under the PFS. This estimate represents an upper bound of potential savings under the PFS for this policy change and does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. We noted in the proposed rule that the estimated effect of the proposed policy could change in this final rule with comment period based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

* * *

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this final rule with comment period, we are setting the CY 2019 ASC relative payment weights by scaling the CY 2019 OPPS relative payment weights by the ASC scalar of 0.8792. The estimated effects of the updated relative payment weights on payment

rates are varied and are reflected in the estimated payments displayed in Tables 63 and 64 below.

* * *

Dated: October 26, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 29, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018-24243 Filed 11–2–18; 8:45 am]

42 U.S.C.A. § 1395*l*

§ 1395*l*. Payment of benefits

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1395k(a)(1) of this title—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the

amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1)(for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1395m-1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,,[1] (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to clinical social worker services under section 1395x(s)(2)(N) of this title, the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), (G) with respect to facility services furnished in connection with a

[1] So in original.

surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system, (H) with respect to services of a certified registered nurse anesthetist under section 1395x(s)(11) of this title, the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w-4 of this title) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection *(l)*, (I) with respect to covered items (described in section 1395m(a)(13) of this title), the amounts paid shall be the amounts described in section 1395m(a)(1) of this title, and[2] (J) with respect to expenses incurred for radiologist services (as defined in section 1395m(b)(6) of this title), subject to section 1395w-4 of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1395m(b) of this title, (K) with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the

[2] So in original. The word "and" probably should not appear.

Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1395w-4 of this title for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1395x(s)(2)(M) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1395m(h)(4) of this title), the amounts paid shall be the amounts described in section 1395m(h)(1) of this title, (N) with respect to expenses incurred for physicians' services (as defined in section 1395w-4(j)(3) of this title) other than personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amounts paid shall be 80 percent of the payment basis determined under section 1395w-4(a)(1) of this title, (O) with respect to services described in section 1395x(s)(2)(K) of this title (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1395w-4 of this title, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with

respect to surgical dressings, the amounts paid shall be the amounts determined under section 1395m(i) of this title, (Q) with respect to items or services for which fee schedules are established pursuant to section 1395u(s) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1395m*(l)* of this title and (ii) with respect to ambulance services described in section 1395m*(l)*(8) of this title, the amounts paid shall be the amounts determined under section 1395m(g) of this title for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1395x(zz) of this title)) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1395u(*o*) of this title (or, if applicable, under section 1395w-3, 1395w-3a, or 1395w-3b of this title), (T) with respect to medical nutrition therapy services (as defined in section 1395x(vv) of this title), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1395w-4(b) of this title for the same services if

furnished by a physician, (U) with respect to facility fees described in section 1395m(m)(2)(B) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1395u(s) items), with respect to competitively priced items and services (described in section 1395w-3(a)(2) of this title) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1395w-3(b)(5) of this title, (W) with respect to additional preventive services (as defined in section 1395x(ddd)(1) of this title), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1395w-4 of this title, (Y) subject to subsection (dd), with respect to preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any

indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1395m(*o*) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1395m(s) of this title) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1395m(u) of this title, (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1395m(w) of this title less any copayment required as specified by the Secretary, and (DD) with respect to a specified COVID-19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, the amounts paid shall be 100 percent of the payment amount

otherwise recognized under such respective specified outpatient payment provision for such service,;[1]

(2) in the case of services described in section 1395k(a)(2) of this title (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1395rr of this title)—

(A) with respect to home health services (other than a covered osteoporosis drug)(as defined in section 1395x(kk) of this title), the amount determined under the prospective payment system under section 1395fff of this title;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1395ww of this title or section 1395yy(e)(9) of this title)—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(II) the customary charges with respect to such services,

less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the

[1] So in original.

satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1395f(b)(2) of this title, or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1395f(b)(3) of this title are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1395x(p) of this title, 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule determined under subsection (h)(1)(for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395cc of this title) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1395m-1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having

an agreement under section 1395cc of this title) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1395x(s)(3) of this title (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1395x(kk) of this title) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1395x(v) of this title;

(G) with respect to items and services described in section 1395x(s)(10)(A) of this title, the lesser of—

(i) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or,[3] 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 provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title;

(3) in the case of services described in section 1395k(a)(2)(D) of this title—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1395x(v)(1)(A) of this title, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such services (other than for items and services described

[3] See 2010 Amendment note relating to Pub.L. 111-148, § 4103(c)(3)(B).

in section 1395x(s)(10)(A) of this title) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1395k(a)(2)(D) of this title that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1395w-23(a)(4) of this title, the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1395m(*o*) of this title, under such section (calculated as if "100 percent" were substituted for "80 percent" in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1395w-27(e)(3)(B) of this title;

(4) in the case of facility services described in section 1395k(a)(2)(F) of this title, and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to subsection (i)(1)(A), the applicable

amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1395m(a)(13) of this title) the amounts described in section 1395m(a)(1) of this title;

(6) in the case of outpatient critical access hospital services, the amounts described in section 1395m(g) of this title;

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1395m(h)(4) of this title), the amounts described in section 1395m(h) of this title;

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient

hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i), the amounts described in section 1395m(k) of this title;

(9) in the case of services described in section 1395k(a)(2)(E) of this title that are not described in paragraph (8), the amounts described in section 1395m(k) of this title; and

(10) with respect to rural emergency hospital services furnished on or after January 1, 2023, the amounts determined under section 1395m(x) of this title.

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1395m(*o*) of this title. For services furnished on or after January 1, 2022, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(b) Deductible provision

Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for

calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1395r(a)(1) of this title ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1395x(ddd)(3) of this title that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual.,[1] (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title)), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1395cc of this title, or (B) for tests furnished before January 1, 2017, on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1395x(jj) of this title), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1395x(nn) of this title), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as

[1] So in original.

defined in section 1395x(bbb) of this title), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1395x(pp)(1) of this title), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1395x(ww) of this title), (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), (11) such deductible shall not apply with respect to any specified COVID-19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, and (12) such deductible shall not apply with respect[4] a COVID-19 vaccine and its administration described in section 1395x(s)(10)(A) of this title. The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed

[4] So in original. Probably should be followed by "to".

red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395e(a)(2) of this title to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c) Mental disorders

(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62 ½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68 ¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81 ¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

(d) Nonduplication of payments

No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1395e of this title) to have payment made with respect to such services under part A.

(e) Information for determination of amounts due

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f) Maximum rate of payment per visit for independent rural health clinics

(1) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in

hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided prior to April 1, 2021—

(A) in 1988, after March 31, at $46 per visit, and

(B) in a subsequent year (before April 1, 2021), at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) applicable to primary care services (as defined in section 1395u(i)(4) of this title) furnished as of the first day of that year.

(2) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic (other than a rural health clinic described in paragraph (3)(B)), the Secretary shall establish such limit, for services provided—

(A) in 2021, after March 31, at $100 per visit;

(B) in 2022, at $113 per visit;

(C) in 2023, at $126 per visit;

(D) in 2024, at $139 per visit;

(E) in 2025, at $152 per visit;

(F) in 2026, at $165 per visit;

(G) in 2027, at $178 per visit;

(H) in 2028, at $190 per visit; and

(I) in a subsequent year, at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year.

(3)(A) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic described in subparagraph (B), the Secretary shall establish such limit, with respect to each such rural health clinic, for services provided—

(i) in 2021, after March 31, at an amount equal to the greater of—

(I) with respect to a rural health clinic that had a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or

(bb) the limit described in paragraph (2)(A); and

(II) with respect to a rural health clinic that did not have a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2021; or

(bb) the limit described in paragraph (2)(A); and

(ii) in a subsequent year, at an amount equal to the greater of—

(I) the amount established under subclause (I) or (II) of clause (i), as applicable, or this subclause for the previous year with respect

to such rural health clinic, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or

(II) the limit established under paragraph (2) for such subsequent year.

(B) A rural health clinic described in this subparagraph is a rural health clinic that—

(i) as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver under subsection (b)(1)(A) of section 1320b-5 of this title during the emergency period described in subsection (g)(1)(B) of such section); and

(ii)(I) as of December 31, 2020, was enrolled under section 1395cc(j) of this title (including temporary enrollment during such emergency period for such emergency period); or

(II) submitted an application for enrollment under section 1395cc(j) of this title (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.

(g) Physical therapy services

(1)(A) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1395x(p) of this title and speech-language pathology services of the type described in such section through the application of section 1395x(*ll*)(2) of this title, but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical

therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1395x(p) of this title, speech-language pathology services of the type described in such section through the application of section 1395x(*ll*)(2) of this title, and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3)(A) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1395x(p) of this title (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1395x(g) of this title and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1395x(p) of this title through the operation of section 1395x(g) of this title and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and

ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of February 22, 2012) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical

review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

[(D) Redesignated (g)(8)]

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a "therapy provider") using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this subchapter.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this subchapter or has not

previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group[5] that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1395ddd(h) of this title for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented, except as such process is applied under paragraph (7)(B).

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

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[5] So in original. Probably should be preceded by "a".

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1395m(g) of this title, the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1395m(k)(1)(B) of this title instead of being paid under section 1395m(g) of this title.

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1395m(g) of this title.

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

(A) Inclusion of appropriate modifier

The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(B) Targeted medical review for certain services above threshold

(i) In general

In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such

services shall be subject to the process for medical review implemented under paragraph (5)(E).

(ii) Threshold

The threshold under this clause for—

(I) a year before 2028, is $3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for 2028; and

(III) a subsequent year, is the amount specified in this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year;

except that if an increase under subclause (II) or (III) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(iii) Application

The threshold under clause (ii) shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(iv) Funding

For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000 for each fiscal year beginning with

fiscal year 2018, to remain available until expended. Such funds may not be used by a contractor under section 1395ddd(h) of this title for medical reviews under this subparagraph.

(8) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1395pp of this title shall apply in the same manner as such section applies to a denial that is made by reason of section 1395y(a)(1) of this title.

(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate

(1)(A) Subject to section 1395m(d)(1) of this title, the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1395x(*oo*) of this title consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1395u(b)(3) of this title for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before April 1, 2014,

subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1395u(b)(3) of this title performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017) or under section 1395m-1 of this title (for tests furnished on or after January 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this subchapter for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to

individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1395cc of this title, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)),[6] receives requests for testing during the year in which the test is performed[6] are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1395x(w)(1) of this title) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a

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[6] So in original. The comma after "subclause (II))" probably should follow "is performed".

physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1395cc of this title.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1395u(j) of this title in the same manner such paragraphs apply[7] with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, in the case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4) and section 1395m-1 of this title, the Secretary shall

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[7] So in original. Probably should be "such paragraph applies".

establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes

representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i) Outpatient surgery

(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an

ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1395k(a)(2)(F)(i) of this title), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this subchapter than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this subchapter than would have been paid if the

services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system

described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of subsection (t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such subsection,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title.

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost

reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this[8] subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing

[8] So in original. The word "this" probably should not appear.

separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1395k(a)(2)(F)(i) of this title, who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money

penalty of not to exceed $2,000. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of subsection (t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section

1395*l*(t) of this title)[9], including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).

(j) Accrual of interest on balance of excess or deficit not paid

Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1395u(b)(3)(B)(ii) of this title was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments (or, in the case of such a determination made with respect to a payment made on or after March 27, 2020, and during the emergency period described in section 1320b-5(g)(1)(B) of this title under the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation), at a rate of 4 percent).

(k) Hepatitis B vaccine

With respect to services described in section 1395x(s)(10)(B) of this title, the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount

[9] So in original. Closing parenthesis should probably not appear.

or amounts as reasonably reflects the general cost of efficiently providing such services.

(*l*) Fee schedule for services of certified registered nurse anesthetists

(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1395x(s)(11) of this title.

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this subchapter for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this subchapter for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987,

adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this subchapter plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1395u(b)(3) of this title.

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1395w-4(d) of this title for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1395w-4 of this title (or, in the case of services furnished during 1991, the localities used under section 1395u(b) of this title) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—[10]

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1395u(q)(1)(B) of this title for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1395w-4 of this title,

[10] So in original. Probably should be "are—".

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1395w-4 of this title).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1395w-4(a)(5)(B) of this title with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996

shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs[11] (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access

[11] So in original. Probably should be "subparagraph".

hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this subchapter.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1395u(j)(1)(D) of this title.

(m) Incentive payments for physicians' services furnished in underserved areas

(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n) Payments to hospital outpatient departments for radiology; amount; definitions

(1)(A)[12] The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services

[12] So in original. No paragraph "(2)" has been enacted.

described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after April 1, 1989 and for services described in subsection (a)(2)(E)(ii) furnished on or after January 1, 1992) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1395u(b) of this title (or, in the case of services furnished on or after January 1, 1992, under section 1395w-4 of this title), less the amount a provider may

charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title.

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(*o*) Limitation on benefit for payment for therapeutic shoes for individuals with severe diabetic foot disease

(1) In the case of shoes described in section 1395x(s)(12) of this title—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment

applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1395m(h) of this title.

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1395m(h) of this title if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1395x(s)(12) of this title may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1395m(h) of this title, a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this subchapter, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(p) Repealed. Pub. L. 103-432, Title I, § 123(b)(2)(A)(ii), Oct. 31, 1994, 108 Stat. 4411

(q) Requests for payment to include information on referring physician

(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1395nn of this title) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this chapter for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1320a-7 of this title.

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(r) Cap on prevailing charge; billing on assignment-related basis

(1) With respect to services described in section 1395x(s)(2)(K)(ii) of this title (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1396r(a) of this title), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this

part for services described in section 1395x(s)(2)(K)(ii) of this title may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this subchapter.

(s) Other prepaid organizations

The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits

under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title;

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(*l*) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is

classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of

covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of Title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services

in 1999, as though the deductible under subsection (b) did not apply.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD

service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the

conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1395ww(b)(3)(B)(iii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b), to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment

(A) In general

Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment

The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority

In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCs from outlier payments

No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals

(A) In general

The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs

A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 360bb of Title 21 if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy

A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a

hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products

A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) New medical devices, drugs, and biologicals

A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments

The following provisions apply for purposes of determining whether a medical device qualifies

for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories

(I) In general

The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations

The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories

(I) In general

The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) Standard

Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline

Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories

The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect

A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met

A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 360e of Title 21 has been approved with respect to the device, or the device has been cleared for market under section 360(k) of Title 21, or the device is exempt from the requirements of section 360(k) of Title 21 pursuant to subsection (*l*) or (m) of section 360 of Title 21 or section 360j(g) of Title 21.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment

(i) Drugs and biologicals

Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices

Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment

Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1395u(o) of this title (or if the drug or biological is covered under a competitive acquisition contract under section

1395w-3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018 or 2020.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded

If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard

(i) In general

The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application

Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after December 8, 2003, unless—

(I) such application was being made to such drug or biological prior to December 8, 2003; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this subchapter.

(iii) Rule of construction

Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) Pass-through extension for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) Temporary payment rule for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period

beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) Special payment adjustment rules for last quarter of 2018

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD[13] service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

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[13] So in original. Probably should be "a covered OPD".

(J) Additional pass-through extension and special payment adjustment rule for certain diagnostic radiopharmaceuticals

In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

(7) Transitional adjustment to limit decline in payment

(A) Before 2002

Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002

Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and

the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003

Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions

(i) Temporary treatment for certain rural hospitals

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) Permanent treatment for cancer hospitals and children's hospitals

In the case of a hospital described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title, for covered OPD services for which the PPS

amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined

In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this subchapter for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1395cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b).

(F) Pre-BBA amount defined

(i) In general

In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost ratio defined

For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost

report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments

The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments

Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality

The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount

(A) In general

Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is

the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount

The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount

(i) To inpatient hospital deductible amount

In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.

(ii) To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis)

for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) No impact on deductibles

Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under subsection (b).

(E) Computation ignoring outlier and pass-through adjustments

The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in

technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor

If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) Special rule for ambulance services

The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1395x(v)(1)(U) of this title, or, if applicable, the fee schedule established under section 1395m(*l*) of this title.

(11) Special rules for certain hospitals

In the case of hospitals described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) Authorization of adjustment for rural hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates

(A) In general

The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the

Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(*o*) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) Specified covered outpatient drug defined

(i) In general

In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r-8(k)(2) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception

Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B) (ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) Annual GAO surveys in 2004 and 2005

(I) In general

The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations

Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) Subsequent secretarial surveys

The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements

The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost

In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates

Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates

based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs

(i) MedPAC report on drug APC design

The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized

The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs

For purposes of this paragraph:

(i) Sole source drugs

The term "sole source drug" means—

(I) a biological product (as defined under section 1395x(t)(1) of this title); or

(II) a single source drug (as defined in section 1396r-8(k)(7)(A)(iv) of this title).

(ii) Innovator multiple source drugs

The term "innovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(ii) of this title.

(iii) Noninnovator multiple source drugs

The term "noninnovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(iii) of this title.

(G) Reference average wholesale price

The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(*o*) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) Payment for new drugs and biologicals until HCPCS code assigned

With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD

services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) Miscellaneous provisions

(A) Application of reclassification of certain hospitals

If a hospital is being treated as being located in a rural area under section 1395ww(d)(8)(E) of this title, that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCs for drugs

The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished,

adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) Special payment rule

(i) In general

In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) Hospital described

A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1395ww(d)(2)(D) of this title);

(II) classified as a rural referral center under section 1395ww(d)(5)(C) of this title; or

(III) a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title).

(iii) Not budget neutral

In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) Application of appropriate use criteria for certain imaging services

For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1395m(q) of this title.

(F) Payment incentive for the transition from traditional X-ray imaging to digital radiography

Notwithstanding the previous provisions of this subsection:

(i) Limitation on payment for film X-ray imaging services

In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section

(without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) Phased-in limitation on payment for computed radiography imaging services

In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1395w-4(b)(9)(C) of this title)—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) Application without regard to budget neutrality

The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) Implementation

In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) Quality reporting

(A) Reduction in update for failure to report

(i) In general

For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) Non-cumulative application

A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) Form and manner of submission

Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time,

specified by the Secretary for purposes of this paragraph.

(C) Development of outpatient measures

(i) In general

The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) Construction

Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1395ww(b)(3)(B)(viii) of this title.

(D) Replacement of measures

For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) Availability of data

The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review

the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) Authorization of adjustment for cancer hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) Target PCR adjustment

In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1395ww(d)(1)(B)(v) of this title. In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) Floor on area wage adjustment factor for hospital outpatient department services in frontier States

(A) In general

Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) Limitation

This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(20) Not budget neutral application of reduced expenditures resulting from quality incentives for computed tomography

The Secretary shall not take into account the reduced expenditures that result from the application of section 1395m(p) of this title in making any budget neutrality adjustments this[14] subsection.

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal

[14] So in original. Probably should be preceded by "under".

Regulations, as in effect as of November 2, 2015) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) Exception

For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015.

(iii) Deemed treatment for 2017

For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) Alternative exception beginning with 2018

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and

services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after December 13, 2016), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1395cc(j) of this title; and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after December 13, 2016, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) Mid-build requirement described

The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) Exclusion for certain cancer hospitals

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1395ww(d) (1)(B)(v) of this title and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before December 13, 2016, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date; or

(II) in the case of a department that meets such requirements after such date, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) Audit

Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance

with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) Implementation

For purposes of implementing clauses (iii) through (vii) :

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of Title 44 shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

(C) Availability of payment under other payment systems

Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph

(1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) Information needed for implementation

Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1395cc(j) of this title).

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(22) Review and revisions of payments for non-opioid alternative treatments

(A) In general

With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

(B) Priority

In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of

services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

(C) Revisions

If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

(D) Rules of construction

Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

(u) Incentive payments for physician scarcity areas

(1) In general

In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) Determination of ratios of physicians to medicare beneficiaries in area

Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) Number of physicians practicing in the area

The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) Number of medicare beneficiaries residing in the area

The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) Determination of ratios

(i) Primary care ratio

The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) Specialist care ratio

The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) Ranking of counties

The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) Identification of counties

(A) In general

The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined

under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) Periodic revisions

The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) Identification of counties where service is furnished

For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) Special rule

With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, respecting—

(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) Rural census tracts

To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) Physician defined

For purposes of this paragraph, the term "physician" means a physician described in section 1395x(r)(1) of this title and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) Publication of list of counties; posting on website

With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1395w-4 of this title for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) Increase of FQHC payment limits

In the case of services furnished by Federally qualified health centers (as defined in section 1395x(aa)(4) of this title), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year.

(w) Methods of payment

The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) Incentive payments for primary care services

(1) In general

In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) Definitions

In this subsection:

(A) Primary care practitioner

The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1395x(r)(1) of this title) who has a primary

specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1395x(aa)(5) of this title); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) Primary care services

The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) Coordination with other payments

The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) Incentive payments for major surgical procedures furnished in health professional shortage areas

(1) In general

In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) Definitions

In this subsection:

(A) General surgeon

In this subsection, the term "general surgeon" means a physician (as described in section 1395x(r)(1) of this title) who has designated CMS specialty code 02-General Surgery as their primary specialty code in the physician's enrollment under section 1395cc(j) of this title.

(B) Major surgical procedures

The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1395w-4(b) of this title.

(3) Coordination with other payments

The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) Application

The provisions of paragraph[15] (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) Incentive payments for participation in eligible alternative payment models

(1) Payment incentive

(A) In general

In the case of covered professional services furnished by an eligible professional during a year

[15] So in original. Probably should be "paragraphs".

that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) Form of payment

Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) Treatment of payment incentive

Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing

any benchmarks used under the alternative payment model.

(D) Coordination

The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) Qualifying APM participant

For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 and 2020

With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 through 2024

With respect to each of 2021 through 2024, an eligible professional described in either of the following clauses:

(i) Medicare payment threshold option

An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) Combination all-payer and Medicare payment threshold option

An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under subchapter XIX in a State in which no medical home or alternative payment model is available under the State program under that subchapter),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) Requirement

For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1395w-4(q) (2)(B)(i) of this title apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds[16] expected aggregate expenditures; or

(BB) with respect to beneficiaries under subchapter XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1315a(c) of this title.

(C) Beginning in 2025

With respect to 2025 and each subsequent year, an eligible professional described in either of the following clauses:

(i) Medicare payment threshold option

An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) Combination all-payer and Medicare payment threshold option

An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

[16] So in original. Probably should be "exceed".

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under subchapter XIX in a State in which no medical home or alternative payment model is available under the State program under that subchapter),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) Requirement

For purposes of clause (ii)(I) –

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1395w-4(q) (2)(B)(i) of this title apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds[16] expected aggregate expenditures; or

(BB) with respect to beneficiaries under subchapter XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1315a(c) of this title.

(D) Use of patient approach

The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1395w-4(q)(1)(C)(iii) of this title by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate. With respect to 2023 and 2024, the Secretary shall use the same

[16] So in original. Probably should be "exceed".

percentage criteria for counts of patients that are used in 2022.

(3) Additional definitions

In this subsection:

(A) Covered professional services

The term "covered professional services" has the meaning given that term in section 1395w-4(k)(3)(A) of this title.

(B) Eligible professional

The term "eligible professional" has the meaning given that term in section 1395w-4(k)(3)(B) of this title and includes a group that includes such professionals.

(C) Alternative Payment Model (APM)

The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1315a of this title (other than a health care innovation award).

(ii) The shared savings program under section 1395jjj of this title.

(iii) A demonstration under section 1395cc-3 of this title.

(iv) A demonstration required by Federal law.

(D) Eligible alternative payment entity

The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (*o*)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1395w-4(q)(2)(B)(i) of this title; and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1315a(c) of this title.

(4) Limitation

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo*[17] of this title, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

[17] So in original. Probably should be preceded by "section".

(aa) Medical review of spinal subluxation services

(1) In general

The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1395x(r)(5) of this title by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a[1] chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) Medical review

(A) Prior authorization medical review

(i) In general

Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1395x(r)(5) of this title that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the

[1] So in original.

underlying cause that justifies the need for services, such as a diagnosis code.

(ii) Ending application of prior authorization medical review

The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) Early request for prior authorization review permitted

Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) Type of review

The Secretary may use pre-payment review or post-payment review of services described in section 1395x(r)(5) of this title that are not subject to prior authorization medical review under subparagraph (A).

(C) Relationship to law enforcement activities

The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) No payment without prior authorization

With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) Prior authorization determination

The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1395y(a)(1)(A) of this title.

(B) Denial of payment

Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1395y(a)(1)(A) of this title.

(4) Submission of information

A chiropractor described in section 1395x(r)(5) of this title may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) Timeliness

If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of

medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) Application of limitation on beneficiary liability

Where payment may not be made as a result of the application of paragraph (2)(B), section 1395pp of this title shall apply in the same manner as such section applies to a denial that is made by reason of section 1395y(a)(1) of this title.

(7) Review by contractors

The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1395kk-1(a)(4)(G) of this title or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) Multiple services

The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) Construction

With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this chapter.

(10) Implementation

(A) Authority

The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) Administration

Chapter 35 of Title 44 shall not apply to medical review under this subsection.

(bb) Additional payments for certain rural health clinics with physicians or practitioners receiving data 2000 waivers

(1) In general

In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1395x(aa)(1) of this title) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

(2) Application

In order to receive a payment described in paragraph (1), a rural health clinic shall submit to

the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

(3) Requirements

For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

(B) The physician or practitioner first receives a waiver under section 823(g) of Title 21 on or after January 1, 2019.

(4) Funding

For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.

(cc) Specified COVID-19 testing-related services

For purposes of subsection (a)(1)(DD) :

(1) Description

(A) In general

A specified COVID-19 testing-related service described in this paragraph is a medical visit that—

(i) is in any of the categories of HCPCS evaluation and management service codes described in subparagraph (B);

(ii) is furnished during any portion of the emergency period (as defined in section 1320b-5(g)(1)(B) of this title) (beginning on or after March 18, 2020);

(iii) results in an order for or administration of a clinical diagnostic laboratory test described in section 1395w-22(a)(1)(B)(iv)(IV) of this title; and

(iv) relates to the furnishing or administration of such test or to the evaluation of such individual for purposes of determining the need of such individual for such test.

(B) Categories of HCPCS codes

For purposes of subparagraph (A), the categories of HCPCS evaluation and management services codes are the following:

(i) Office and other outpatient services.

(ii) Hospital observation services.

(iii) Emergency department services.

(iv) Nursing facility services.

(v) Domiciliary, rest home, or custodial care services.

(vi) Home services.

(vii) Online digital evaluation and management services.

(2) Specified outpatient payment provision

A specified outpatient payment provision described in this paragraph is any of the following:

(A) The hospital outpatient prospective payment system under subsection (t).

(B) The physician fee schedule under section 1395w-4 of this title.

(C) The prospective payment system developed under section 1395m(*o*) of this title.

(D) Section 1395m(g) of this title, with respect to an outpatient critical access hospital service.

(E) The payment basis determined in regulations pursuant to subsection (a)(3) for rural health clinic services.

(dd) Special coinsurance rule for certain colorectal cancer screening tests.

(1) In general

In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection (a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

(2) Specified percent defined

For purposes of paragraph (1), the term "specified percent" means—

(A) for 2022, 80 percent;

(B) for 2023 through 2026, 85 percent; and

(C) for 2027 through 2029, 90 percent.