

SUPREME COURT OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

ALEX M. AZAR, II, SECRETARY)
OF HEALTH AND HUMAN SERVICES,)
Petitioner,)
v.) No. 17-1484
ALLINA HEALTH SERVICES, ET AL.,)
Respondents.)

Pages: 1 through 64

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Petitioner,)
v.) No. 17-1484
ALLINA HEALTH SERVICES, ET AL.,)
Respondents.)

- - - - -
Washington, D.C.
Tuesday, January 15, 2019

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 11:12 a.m.

APPEARANCES:
EDWIN S. KNEEDLER, Deputy Solicitor General,
Department of Justice, Washington, D.C.;
on behalf of the Petitioner.
PRATIK A. SHAH, ESQ., Washington, D.C.;
on behalf of the Respondents.

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1 P R O C E E D I N G S

2 (11:12 a.m.)

3 CHIEF JUSTICE ROBERTS: We'll hear
4 argument next in Case 17-1484, Azar versus
5 Allina Health Services.

6 Mr. Kneedler.

7 ORAL ARGUMENT OF EDWIN S. KNEEDLER

8 ON BEHALF OF THE PETITIONER

9 MR. KNEEDLER: Mr. Chief Justice, and
10 may it please the Court:

11 Section 1395hh did not require CMS to
12 go through notice-and-comment rulemaking before
13 it could furnish its calculation of one
14 component of a hospital's reimbursement to the
15 contractors that perform the initial
16 determination of reimbursement for the agency.

17 That calculation was not binding on
18 the agency, the courts, or Respondents, and it
19 could be challenged on administrative appeal,
20 as, in fact, Respondents did here.

21 JUSTICE SOTOMAYOR: I have a -- a sort
22 of problem with this. And I know you say that,
23 but I don't know how you take this outside of
24 being a policy, meaning it's applying to every
25 single provider uniformly. I don't know the

1 basis that you could have a individual
2 adjudication. And what would happen? The
3 board would look at it and say we're not going
4 to listen, even though we're required to
5 listen, to the agency's position; we're going
6 to tell them they're wrong?

7 If one case tells you the agency is
8 wrong, does that case then become the new
9 policy? Or -- or are you -- I'm a little lost
10 as to how this is not a agency policy.

11 MR. KNEEDLER: So several points.

12 JUSTICE SOTOMAYOR: A statement of
13 policy.

14 MR. KNEEDLER: Several points, Justice
15 Sotomayor. And the -- the first is that we are
16 relying on the operative language in 1395hh,
17 whether it's called a -- whether the issuance
18 is called a policy or a requirement or whatever
19 the agency calls it. It is only -- it only
20 triggers notice-and-comment rulemaking if it
21 establishes or changes a substantive legal
22 standard. And that is the --

23 JUSTICE SOTOMAYOR: Well, that's what
24 I'm -- that's what I'm having a problem with.
25 It's every single provider is going to be given

1 a fraction that incorporates your policy, and
2 that binds what they're going to get.

3 MR. KNEEDLER: No, it -- it --

4 JUSTICE SOTOMAYOR: Because they have
5 to use that fraction in the claims they made
6 against you.

7 MR. KNEEDLER: It -- it only governs
8 what the contractor does. The contractor is
9 just like an agency employee, making
10 determinations on behalf of the agency at the
11 first step.

12 When -- when the --

13 JUSTICE SOTOMAYOR: From you -- from
14 the contractor, from the agency, they're only
15 going to get the fraction as you told the
16 contractor to calculate it.

17 MR. KNEEDLER: Only if they don't
18 appeal. And -- and as -- as we point out --

19 JUSTICE SOTOMAYOR: I -- I just don't
20 understand what difference it means -- it means
21 -- I mean, even a regulation or a rule may have
22 legal meaning only until it's accepted, but
23 even a rule can be challenged later on appeal.

24 The grounds for that challenge might
25 be different, but I can go into court and say

1 it's ultra vires. I can go into court and say
2 it's not supported by the statute. It's not
3 binding in -- in any meaningful way, other than
4 that's what the agency's going to do.

5 MR. KNEEDLER: Well, if I -- if I may,
6 in our view, 1395hh codifies for the Medicare
7 program what this Court referred to in Chrysler
8 Corporation as the central distinction in the
9 APA between substantive and interpretive rules.

10 And this Court in Guernsey --

11 JUSTICE SOTOMAYOR: Well, the problem
12 I have is that the provision adds something.
13 It's not just rule or regulation; it's
14 statement of policy. And it seems to suggest
15 to me that there's some interpretive rules that
16 are encompassed by that. Now which ones is the
17 open question.

18 But it does seem to suggest that it's
19 broader than the APA ever was, because the APA
20 only talks about rules.

21 MR. KNEEDLER: Well, again, several
22 points -- several points about that. This
23 Court's decision in Guernsey Memorial Hospital,
24 which described the general APA standards,
25 distinguished between substantive rules and

1 interpretive rules.

2 And the interpretive rule there was
3 something in the provider reimbursement manual
4 which, just as here, bound the contractor but
5 could be changed -- or could be challenged --

6 JUSTICE SOTOMAYOR: Mr. Kneedler, why
7 didn't --

8 MR. KNEEDLER: -- and set aside on
9 appeal.

10 JUSTICE SOTOMAYOR: -- why didn't
11 Congress just say this is like the APA? Why
12 does it change the language at all?

13 MR. KNEEDLER: Well --

14 JUSTICE SOTOMAYOR: I have to give
15 some meaning different than the APA to
16 Congress's express choice of a different
17 articulation of the standard.

18 MR. KNEEDLER: Well, first of all,
19 when -- when Congress first enacted the
20 provisions or amended the provisions in the
21 rulemaking in 1986, it said certain regulations
22 -- regulations have to go through notice and
23 comment. It didn't define regulation at that
24 point.

25 But the conference report said this

1 does not require notice-and-comment rulemaking
2 for interpretive rules or other things that are
3 not now subject to that requirement.

4 Then, in 1987, Congress revisited the
5 -- the provision. And if you look at page 34
6 of our brief, we -- we set out the House
7 version, the version that was passed by the
8 House, and then -- and contrast that to the
9 version that was finally enacted.

10 The House -- the House version said no
11 rule requirement or other statement of policy
12 that has or may have a significant effect on
13 the payment for services can go into effect
14 unless promulgated through notice-and-comment
15 rulemaking. That was changed in conference.

16 And the enacted language kept
17 everything but substituted for that italicized
18 language the phrase "that has" -- that --
19 excuse me, "that establishes or changes a
20 substantive legal standard."

21 JUSTICE BREYER: Is -- is this right?
22 I mean, I -- it's very complicated, what you're
23 saying. I thought it was quite simple, that
24 for a long time in Medicare they didn't have to
25 follow the APA. All right?

1 Then Congress passes a statute and
2 says, in this area, you do. So the reason it
3 says no rule, requirement, or other statement
4 of policy is they have certain policy
5 statements in mind, certain requirements in
6 mind, and certain rules in mind, namely, those
7 that establish or change a substantive legal
8 standard.

9 MR. KNEEDLER: And that --

10 JUSTICE BREYER: And, basically, what
11 they're doing is saying to the agency, don't
12 run around this. We're not going to permit a
13 run-around, where what you do is you change the
14 legal standard and you call what you're doing a
15 statement of policy. So don't run around us,
16 my friend. You follow the APA.

17 Now that is what I took out of your
18 brief, but have I got that right?

19 MR. KNEEDLER: That -- that is exactly
20 -- that is exactly our position. And the --

21 JUSTICE BREYER: So why didn't you say
22 that was the answer to what Justice Sotomayor
23 said?

24 (Laughter.)

25 JUSTICE SOTOMAYOR: Well, the problem

1 I have with that --

2 MR. KNEEDLER: I -- I -- I tried to
3 start down that path --

4 JUSTICE SOTOMAYOR: -- counsel --

5 MR. KNEEDLER: -- but I -- but that --

6 JUSTICE SOTOMAYOR: -- but -- but let
7 me -- let me stop you. If that's what Congress
8 intended, it could have stopped in 1986
9 because, in 1986, it had done what you said.
10 But something -- and you read the House
11 report --

12 MR. KNEEDLER: The House bill.

13 JUSTICE SOTOMAYOR: -- the House
14 bill -- was leading them to believe that a
15 different standard was necessary because they
16 changed it. They had the APA standard in 1986.
17 They chose intentionally to alter it by
18 altering it in '87.

19 And you look at the rejection of the
20 House bill as something that helps you, but I'm
21 not sure how.

22 MR. KNEEDLER: It -- it --

23 JUSTICE SOTOMAYOR: Because it tells
24 me they are significantly concerned about
25 things that make major changes, substantive

1 changes in how people are being paid.

2 MR. KNEEDLER: And -- and here's --
3 here's what matters there, as -- as I pointed
4 out. Congress substituted has or may have a
5 significant effect. Maybe that would sweep in
6 ordinary statements of policy or interpretive
7 rules. But the -- the Conference Committee and
8 Congress enacted something that -- that refers
9 only to substantive legal standards.

10 And the committee report said this
11 language reflects recent court rulings. The
12 recent court rulings could only be APA rulings
13 because there was nothing else that would have
14 governed Medicare.

15 And, in fact, as we point out in our
16 brief, there was an American Hospital
17 Association case decided, I think, just a
18 matter of several weeks before the Conference
19 Committee that was very similar to this, and it
20 involved instructions affecting peer review
21 organizations, which are contractors that
22 operate on behalf of HHS under the Medicare
23 program.

24 And the court there drew a sharp
25 distinction between substantive rules on the

1 one hand and interpretive and procedural rules
2 on the other hand.

3 JUSTICE BREYER: So the answer is that
4 it didn't do what it's trying to do in 1986.
5 What it talked about was any regulation, which
6 could have included interpretive regulations.

7 I would have found out, because I read
8 the House reports. But those who think they're
9 irrelevant might not have understood the
10 statute.

11 And, moreover, there was an argument
12 going on in the D.C. Circuit about what is a
13 legislative rule. Is it just important versus
14 unimportant, or is it legally binding versus
15 non-legally binding no matter how unimportant?

16 All right. That's what they're
17 thinking about. And it's confused. And the
18 1987 statute clarifies it.

19 MR. KNEEDLER: Yes. We --

20 JUSTICE BREYER: Am I right or not
21 right?

22 MR. KNEEDLER: Yes, we agree. But --
23 but all -- but 1986, we think, makes that clear
24 too. Not only the conference report, which
25 specifically says interpretive rules are not

1 covered, in fact, nothing's covered that wasn't
2 already covered by the APA, but the -- the --
3 the term "regulation" as used itself connotes a
4 -- a substantive rule, a -- a legislative type
5 rule.

6 People may talk about interpretive
7 rules. You don't usually talk about
8 interpretive regulations.

9 JUSTICE GORSUCH: Mr. Kneedler, this
10 is where I get stuck. And I'm -- I'm -- I'm
11 focusing more on the language of the statute, I
12 confess, than -- than the history, which I've
13 read but I -- I find confused, as Justice
14 Breyer suggests.

15 So (a)(2) says that any rule,
16 requirement, or other statement of policy that
17 establishes a substantive legal change has to
18 go through informal rulemaking, not even formal
19 rulemaking. And so, really, the question all
20 boils down to what does "substantive" mean, I
21 think, as -- as -- as I understand it.

22 And the import of that in the
23 government's view is that it's binding, as
24 opposed to an interpretive rule, borrowing
25 language from the APA. And your friend on the

1 other side reads substantive, as it's often
2 read elsewhere in the law, as material or
3 affecting private rights, as opposed to
4 procedural.

5 And both seem to me pretty plausible
6 interpretations of that word. And -- and the
7 strikes against you, as I see it from the text
8 of the statute, are a few.

9 First, the statute speaks of
10 statements of policy as being substantive.
11 But, of course, in APA language, statements of
12 policy are interpretive. They're not
13 substantive. They don't bind the agency in any
14 reasonable sense.

15 It speaks of substantive changes in an
16 interpretive rule in (e). And, of course,
17 that's like a -- a complete incoherent
18 statement in APA language, but entirely
19 coherent in the language of the law if
20 "substantive" means material.

21 And then, of course, the statute also
22 adopts the APA good faith -- the good clause
23 exception to -- to -- to rulemaking verbatim.
24 And it clearly doesn't adopt the substantive
25 interpretive language verbatim, which is right

1 next door in -- in the APA. I mean, it's the
2 next section.

3 And you're asking us to think that
4 Congress recreated that section in this statute
5 through this rather oblique mechanism.

6 So, there, I've put my cards on the
7 table. Tell me where I've gone wrong.

8 MR. KNEEDLER: Okay. Starting with
9 the good cause exception, as -- as we say, in
10 our view, the statute only applies to
11 substantive or legislative rules. And the good
12 cause exception under the APA applies to things
13 that have to go through notice-and-comment
14 rulemaking, which are substantive rules, so it
15 was necessary to incorporate that.

16 But, in -- in our view, the text of
17 the provision, which refers only to substantive
18 legal standards, does not include interpretive
19 rules to begin with or procedural rules for
20 that matter, so there's no need to have an
21 express exception because the operative text
22 excludes it.

23 With respect to the substantive change
24 in regulations under (e)(1), it does not say
25 substantive legal standard, which is the

1 operative language in -- in (a)(2). It says a
2 substantive change.

3 And we think "substantive" means in
4 substance, as opposed to perhaps form or
5 wording or something like that.

6 JUSTICE KAGAN: But then you would be
7 using the word "substantive" in two different
8 ways in two very nearby provisions, wouldn't
9 you?

10 MR. KNEEDLER: Well, but we -- but we
11 think that they -- that they have a different
12 effect. But even -- but even -- even if you
13 said an interpretive rule can address something
14 of substance, it's -- for example, if it's
15 interpreting a statute or a regulation, it may
16 have some effect as a substantive matter, but
17 it is not binding.

18 And what this Court has said in -- in
19 Chrysler Corporation, said it in Guernsey
20 Memorial Hospital, which deals with this very
21 program, a substantive rule is one that has the
22 force and effect of law. An interpretive rule
23 does not. It simply explains the agency's
24 construction of the statutes and rules that it
25 implements. So --

1 JUSTICE GORSUCH: Mr. Kneedler,
2 there's a lot of words there, but I'm not sure
3 there's an answer to Justice Kagan's question.
4 So I'm -- I'm going to give you an opportunity
5 to try again, because it's very important to me
6 as well.

7 Aren't you using the word
8 "substantive" in two different senses, first in
9 the APA's -- what I call the APA sense in (a),
10 and then what I'll call the other traditional
11 legal sense in (e)? So you're conceding to
12 your colleague on the other side that it is
13 used in that sense at least in (e), I believe.

14 MR. KNEEDLER: Well, it -- it doesn't
15 say substantive rule or substantive standard,
16 which would be the --

17 JUSTICE GORSUCH: Substantive -- it
18 says substantive change to an interpretive
19 rule.

20 MR. KNEEDLER: Right.

21 JUSTICE GORSUCH: Which is a nonsense
22 under your view, I believe.

23 MR. KNEEDLER: But -- but substantive
24 there, we -- we think in substance is
25 whatever -- no, I'm -- I'm -- I'm serious, is

1 what it refers to. It's not in form. It's
2 meaningful.

3 But beyond that, the -- the subsequent
4 words used in the section refer to regulations,
5 manual instructions, interpretive rules,
6 statements of policy. It is distinguishing
7 regulations, which are the things that have to
8 go through notice-and-comment under (a), from
9 the subsequent things, manual instructions,
10 interpretive rules, which do not.

11 JUSTICE GORSUCH: Again, a lot of
12 words, but I think at the end of the day you
13 are agreeing that Congress is using that word
14 in two different senses, right?

15 MR. KNEEDLER: We -- we -- we think
16 the phrase "substantive change" here is
17 different from substantive legal standard,
18 which is -- we think is the same as substantive
19 -- as substantive rule.

20 And, I'm sorry, I -- I forgot the
21 third point you asked me.

22 JUSTICE KAGAN: Statement of policy,
23 because that's hanging me up too.

24 MR. KNEEDLER: Okay. State --
25 statement of policy, again, frankly, I think

1 that is an artifact of the House version of the
2 -- of the bill. If you go back to page 34, it
3 read off no rule, requirement, or other
4 statement of policy that has or may have a
5 significant effect.

6 It's possible that a statement of
7 policy, or an interpretive rule, could have a
8 significant effect on -- on --

9 JUSTICE SOTOMAYOR: This one does.

10 MR. KNEEDLER: -- interpretation, but
11 it doesn't have the force of law.

12 JUSTICE KAGAN: So you're -- you're
13 agreeing it's incoherent as written. It's just
14 that when the language was different it was not
15 incoherent?

16 MR. KNEEDLER: Well --

17 JUSTICE KAGAN: As written, it's
18 incoherent because a statement of policy is, by
19 definition, not a substantive rule?

20 MR. KNEEDLER: Yes, but I think it --
21 I think it serves the purpose that Justice
22 Breyer was identifying, basically saying we
23 don't care what you call it, whether you call
24 it a rule, whether you call it a requirement,
25 whether you call it a statement of policy.

1 A rule, after all, includes
2 interpretive rules. So no matter what you call
3 it, a rule, a requirement, or a statement of
4 policy, it -- it covers -- it's only covered if
5 it would have established or changed a
6 substantive legal standard.

7 And, in fact, the conference report on
8 the 1987 amendment specifically stresses --

9 JUSTICE GORSUCH: What would be the --
10 MR. KNEEDLER: -- that it only covers
11 --

12 JUSTICE GORSUCH: What would be the
13 point --

14 MR. KNEEDLER: -- substantive legal
15 standards.

16 JUSTICE GORSUCH: What would be the
17 point of that, though, if a statement of policy
18 couldn't have operative legal effect on anyone
19 anyway?

20 MR. KNEEDLER: Well, again, if -- if
21 -- if that was the --

22 JUSTICE GORSUCH: I mean, a party
23 would simply say that's just a statement of
24 policy. Have a nice day.

25 MR. KNEEDLER: Well, but if -- but if

1 it -- if it purports to, as the language the
2 Court used in Chrysler, to establish a
3 substantive legal standard, it's not just a
4 statement of policy. It's called a statement
5 of policy. Then it actually describes --

6 JUSTICE GORSUCH: Well, then it's not
7 a statement -- then the argument would be it's
8 not a statement of policy, right?

9 MR. KNEEDLER: Right, that -- that --
10 that is true, but that -- but that --

11 JUSTICE GORSUCH: Okay.

12 MR. KNEEDLER: -- that doesn't mean
13 that -- that doesn't mean it's not -- it's not
14 a statement of policy within the precise
15 meaning of the APA.

16 JUSTICE BREYER: Well, they don't want
17 a run-around.

18 MR. KNEEDLER: Right.

19 JUSTICE BREYER: But, (e), they don't
20 run around it by calling it a statement of
21 policy when you're --

22 MR. KNEEDLER: Right.

23 JUSTICE BREYER: -- changing the
24 substantive --

25 JUSTICE KAGAN: Yes, but it's at least

1 --

2 JUSTICE BREYER: And -- and I have a
3 different question, which is (e), which is
4 because they are using the word "substantive
5 change" there possibly in a different sense.

6 So -- so -- so I -- I agree with that,
7 and I -- but I thought that (e) has something
8 to do that's not involved here. (e) is a kind
9 of codification of a different common law rule
10 of administrative law that, when you do
11 something retroactively that's important, Mr.
12 Agency, you better have a reason. You better
13 look at why you've changed it.

14 MR. KNEEDLER: Right.

15 JUSTICE BREYER: If you're changing
16 policy, go look at it and explain it to us.

17 MR. KNEEDLER: Right.

18 JUSTICE BREYER: Something this Court
19 has said many, many times.

20 MR. KNEEDLER: Right.

21 JUSTICE BREYER: And I thought that's
22 what (e) is about.

23 MR. KNEEDLER: Yes.

24 JUSTICE BREYER: It's a different
25 subject.

1 MR. KNEEDLER: That -- that is --
2 that's correct in our view. And it talks about
3 a substantive change in regulations, again,
4 which are the things that have to go through
5 notice-and-comment rule -- rulemaking under
6 subsection (a). And then goes on to say manual
7 instructions, interpretive rules, statements of
8 policy or guidelines, which do not have the
9 force and effect of law, they are not
10 substantive rules or, in the language here,
11 they do not establish or change substantive
12 legal standards.

13 JUSTICE KAGAN: May -- may --

14 MR. KNEEDLER: And so it distinguishes
15 right -- right in there the reg -- the sort of
16 regulations that (a) is talking about and these
17 -- these non-binding sorts of things that --
18 that either way they should be made
19 retroactive. If they're interpretive, the
20 interpretation shouldn't be made retroactive
21 unless it -- it goes through -- unless the
22 agency makes it specified.

23 JUSTICE KAGAN: May -- may I take you
24 back, Mr. Kneedler, to one of Justice
25 Sotomayor's original questions, which is just

1 what, on your theory, this provision ends up
2 actually accomplishing?

3 Because, as I understand the 19 -- the
4 1986, the -- the prior year's provision,
5 Congress essentially already said, for Medicare
6 substantive rules, you have to go through
7 notice and comment. And I understand how this
8 would have been different if it was the
9 original version of the thing, the "has or may
10 have a significant effect."

11 But, as written, on your theory, it
12 seems to just repeat the 1986 command, doesn't
13 it?

14 MR. KNEEDLER: Well, again, the House
15 would have done something broader in 1987. And
16 I -- and I think that the -- I think the Court
17 should realize that --

18 JUSTICE KAGAN: But are you saying --
19 I want to make sure I understand this. Are you
20 saying that the compromise was essentially to
21 just repeat the 1986 provision?

22 MR. KNEEDLER: Yes. I mean, I think
23 -- I think that is -- it was carried forward.
24 And the -- and, again, the conference committee
25 report stresses that only things that establish

1 or change a substantive legal standard.

2 And that -- the word "substantive" in
3 the rulemaking context has a -- has a long
4 history in administrative law under the APA.
5 It also -- the distinction -- that very
6 distinction is drawn in Black's Law Dictionary,
7 as we explain in our -- in our brief.

8 JUSTICE KAGAN: I mean, it is a little
9 bit odd, don't you agree, Mr. Kneedler,
10 because, if the compromise was not to do
11 anything beyond 1986, then you would think that
12 people would just say, okay, let's not do it.
13 Not put in a new -- a new -- a new statute
14 saying precisely the same thing.

15 MR. KNEEDLER: Well, the -- the bill
16 was in conference -- in conference at that
17 point, and there were several other things that
18 were in the bill at that point. This is --
19 this change was not the only one.

20 The bill was in conference, and they
21 -- the conference committee decided that
22 something should be enacted, rather than
23 nothing done at all. But, as to this
24 provision, we think that it -- that --

25 JUSTICE GORSUCH: It's entirely

1 superfluous?

2 MR. KNEEDLER: I -- I -- I don't think
3 it's --

4 JUSTICE GORSUCH: It does nothing?

5 MR. KNEEDLER: No, I don't think it's
6 superfluous.

7 JUSTICE GORSUCH: It does nothing new?

8 MR. KNEEDLER: Well, it -- it -- it
9 substitutes -- it -- it elaborates -- it
10 elaborates on --

11 JUSTICE GORSUCH: But substantively --
12 sorry -- it does nothing new?

13 MR. KNEEDLER: No, it -- it -- it
14 reiterates through the use of such --

15 JUSTICE GORSUCH: It reiterates, okay.
16 It reiterates what's already the law --

17 MR. KNEEDLER: Well, it was not -- it
18 was not in the --

19 JUSTICE GORSUCH: -- which is to say
20 it is superfluous.

21 MR. KNEEDLER: It was not in the
22 statute in 1986.

23 JUSTICE GORSUCH: Can I -- can I take
24 you --

25 MR. KNEEDLER: The statute referred to

1 regulation --

2 JUSTICE GORSUCH: Can I take you back
3 just to one other problem I have? You want us
4 to -- to -- to view this statute as very
5 carefully using APA terminology when it comes
6 to substantive. But, when it comes to
7 statements of policy, you want us to ignore the
8 fact that what -- what the APA -- how it treats
9 them and say even faux statements of policy
10 that are really rules and requirements and
11 regulations, that's what it's aiming at. Isn't
12 that a problem for you too?

13 MR. KNEEDLER: No, I don't -- I don't
14 think so because the -- the statement of policy
15 is in the opening clause, which refers to
16 rules, which could include interpretive rules,
17 requirement, or statement of policy.

18 Those are descriptions of the kind of
19 agency issues --

20 JUSTICE SOTOMAYOR: But when is ever a
21 statement of policy binding?

22 MR. KNEEDLER: Pardon me?

23 JUSTICE SOTOMAYOR: Meaning, when is a
24 statement -- if it's not a rule or regulation,
25 if it's just a statement of policy, when is it

1 ever binding as you've defined "binding"?

2 MR. KNEEDLER: I --

3 JUSTICE SOTOMAYOR: Isn't policy
4 something that can be challenged?

5 MR. KNEEDLER: It -- it -- it is, but
6 I think it's important for the Court to focus
7 on the -- on the operative language, which is
8 whether it changes -- establishes or changes a
9 substantive legal standard. That's what
10 Congress enacted.

11 I'd also like to point out what the
12 consequences of this for the Medicare program
13 are. As -- as this Court has pointed out in
14 Guernsey Memorial Hospital and other cases, the
15 Medicare program has, you know, hundreds of
16 pages of statutes, probably thousands of pages
17 of regulations, but the Court has recognized
18 that that can't answer all questions that come
19 up.

20 And -- and the Court in Guernsey
21 recognized the importance of interpretive
22 materials like, in that case, a provision in
23 the provider reimbursement manual. There are
24 similar manuals governing the program integrity
25 for hospitals and doctors and -- and -- and

1 whatnot. There are still reimbursement issues
2 that are -- that are fleshed out in the manual.

3 JUSTICE SOTOMAYOR: But I look at the
4 subsequent history of this in -- in the D.C.
5 Circuit, and I look at Clarian Health West, and
6 your fears there are overstated. A fairly
7 significant change was held not to be
8 encompassed by this provision because it really
9 was just following the statute.

10 This is filling a gap in the statute.
11 I don't know what else is clearly more a policy
12 than that when you're filling in a gap as
13 opposed to interpreting a statute. And that
14 seems to be the distinction the D.C. -- D.C.
15 Circuit is applying.

16 MR. KNEEDLER: Well, Clarian did not
17 go to the substantive provisions for
18 reimbursement. It had to do with a procedure
19 for various screening.

20 JUSTICE SOTOMAYOR: That's my point.
21 That's my point.

22 MR. KNEEDLER: Yes, but it --

23 JUSTICE SOTOMAYOR: Which is not
24 everything is going to come under this.

25 MR. KNEEDLER: It's not everything,

1 but it -- but it -- but it certainly would
2 subject to notice-and-comment rule --
3 rulemaking a broad swath of what has never been
4 done. This is --

5 JUSTICE GORSUCH: Well, on that -- on
6 that --

7 MR. KNEEDLER: -- this is 30 years
8 later in HHS --

9 JUSTICE GORSUCH: -- on that -- on
10 that, though, I don't doubt it's more
11 convenient for the government to proceed
12 through adjudication of an individual case and
13 announce a new rule that applies to the whole
14 of society without inviting comment and
15 providing notice to everyone affected. Surely,
16 I -- I get that that's easier and preferable,
17 certainly more efficient.

18 But couldn't Congress make rationally
19 an alternative decision that informal
20 rulemaking, not even formal rulemaking, that's
21 gone by the boards, but just informal notice
22 and comment to affected parties in something as
23 significant as changing the formula for
24 Medicare for all Medicare providers nationwide,
25 that maybe they should have 60 days to at least

1 throw in their comments.

2 MR. KNEEDLER: Well, first of all, the
3 agency has tried to go through
4 notice-and-comment rulemaking twice on this.
5 It did -- it did it in 2004, when the issue was
6 brought to its attention. It did it in 2013.
7 It recognizes that.

8 But what it did here was -- was not --
9 not establish a binding provision that has the
10 force and effect of law but simply furnish
11 fractions to the contractors who were
12 performing calculations at the very first stage
13 of the -- of the process.

14 JUSTICE KAGAN: Could I very quickly
15 ask you, given Clarian Health, what
16 consequences are you afraid of?

17 MR. KNEEDLER: Afraid of, again, the
18 broad swath of -- of manual provisions that --
19 I mean, that -- that really just dealt with
20 procedures. I mean, I -- in -- in one respect,
21 you could look at it as -- as recognizing the
22 procedures. Procedural rules are not covered
23 by notice and comment under the APA. A
24 procedure about how contractors are supposed to
25 evaluate certain situations without changing

1 substantive standards isn't -- isn't covered.

2 And that's our -- you know, when it
3 comes to interpretive rules, that's our
4 position, because they -- they explain the
5 agency's own interpretation, but it's the
6 statute that governs, not -- and this is not a
7 regulation that establishes a substantive legal
8 standard on its own terms.

9 If I may reserve the balance of my
10 time.

11 CHIEF JUSTICE ROBERTS: Thank you,
12 Mr. Kneedler.

13 Mr. Shah.

14 ORAL ARGUMENT OF PRATIK A. SHAH
15 ON BEHALF OF THE RESPONDENTS

16 MR. SHAH: Mr. Chief Justice, and may
17 it please the Court:

18 By making the legal determination to
19 count Part C days as Part A entitled days in
20 the Medicare fraction, the agency's 2014
21 issuance reduced the payment right of hospitals
22 nationwide by -- and this is according to the
23 agency's own estimate -- billions of dollars.
24 That is --

25 CHIEF JUSTICE ROBERTS: But it's not

1 -- it's not binding at all.

2 MR. SHAH: Well, Your Honor --

3 CHIEF JUSTICE ROBERTS: Interim
4 calculation.

5 MR. SHAH: I -- I think it's binding
6 in every normal sense of the word. Let me give
7 you two responses. First, let me address your
8 concern on binding as a factual matter and then
9 tell you why it's legally irrelevant.

10 First, as a factual matter, they call
11 it just an internal instruction. The fact is
12 the contractors are the ones who make the final
13 payment determination. How this regime works
14 is the hospitals submit a cost report form that
15 has all the data on it. The contractors then
16 use the fractions from the agency, and they
17 then compute the final adjustment that the
18 hospital is owed.

19 That is then a final binding payment
20 determination. That's it. That's how much the
21 hospital is owed, unless the hospitals could do
22 an administrative appeal or they can sue in
23 court.

24 If you don't do the administrative
25 appeal or sue in court, there's no doubt about

1 it, it's in the reg, that is your final
2 determination of your legal right to payment.

3 Now, here --

4 CHIEF JUSTICE ROBERTS: But doesn't it
5 make sense if you've got -- I don't know
6 exactly -- I mean, how many of these interim
7 calculations do they have?

8 MR. SHAH: Well, when you're talking
9 about interim calculations for the DSH
10 adjustment, there's only two calculations.
11 There's the Medicaid -- Medicare fraction and
12 the Medicaid fraction. That is it.

13 And -- and they compute that, and then
14 they give you a number for that adjustment.

15 JUSTICE BREYER: I think in --

16 CHIEF JUSTICE ROBERTS: Well, but, I
17 mean, how many every year or whatever the
18 payment schedule is? My -- my understanding is
19 they were using this to tell you how to
20 calculate what you owe, but not until the, I
21 don't know, the final bill comes in.

22 MR. SHAH: Oh, okay. So, just to
23 clarify here, so this is in the context of a
24 final payment determination.

25 CHIEF JUSTICE ROBERTS: Right.

1 MR. SHAH: So this happens once a
2 year. At the end of the year, the hospital
3 will, after the year is closed, they'll file a
4 cost report form, and the agency will then use
5 that data, along with the Medicare fraction
6 that the agency has given them, and give them a
7 final total for that year.

8 So it's used to -- as a payment total
9 for the end of the year. And then that
10 Medicare fraction is used, just the Medicare
11 fraction, is then used to compute the interim
12 payments for the next year until the next
13 fractions are issued.

14 So all of that is binding, however
15 that word is used. Obviously, it's not in the
16 statute. But the hospitals are stuck with
17 that. That's their payment determination.

18 Their only recourse, of course, is to
19 file an administrative appeal or sue in court.
20 They did that here. And here is what the
21 agency's own board said. We are bound by the
22 agency's action. That is, we lack the legal
23 authority to look behind the policy and
24 adjudicate this.

25 The agency's own board says they can't

1 do that. So for -- for the government --

2 JUSTICE BREYER: Well, then they're
3 wrong, because the SG is telling us that they
4 do have that power.

5 MR. SHAH: Well, okay.

6 JUSTICE BREYER: And so, therefore,
7 your complaint is to go to a court and say they
8 didn't do what they admit they were supposed to
9 do --

10 MR. SHAH: Well, Justice Breyer--

11 JUSTICE BREYER: -- which is that they
12 treat the substantive matter --

13 MR. SHAH: Justice Breyer, the
14 government made that exact argument to the
15 district court, and the district court found
16 that the board was right. They made that --

17 JUSTICE BREYER: That's what both of
18 these things seem to me to be somewhat side
19 issues. I understand why they give color to
20 the problem.

21 MR. SHAH: Right.

22 JUSTICE BREYER: And I accept that.
23 But the basic problem to me is whether or not
24 this statute, in using words like policy and so
25 forth, is saying: Agency, when you have a

1 legislative rule, which is defined as a rule
2 that establishes or changes a legal --
3 substantive legal standard, when you have that
4 kind of rule and don't hide it under a
5 statement of policy or some other way, when
6 it's doing that, use notice-and-comment.

7 Now, if you aren't doing that, you can
8 use notice-and-comment. You're more free to do
9 what you want.

10 Now that's basically their argument.

11 MR. SHAH: Right.

12 JUSTICE BREYER: That has considerable
13 importance even beyond this area. And so I'd
14 like you at some -- you know, to get to your
15 view on that.

16 MR. SHAH: Sure. Okay. So, Your
17 Honor, that -- that argument makes no sense
18 because it goes -- it doesn't go any further
19 than the 1986 enactment that we've already
20 discussed.

21 And even under the APA, if you call a
22 legislative rule a ham sandwich, that doesn't
23 get you out of the notice-and-comment
24 requirement. If you called an interpretive
25 rule or a statement of policy, there is an

1 exception for those, but if it's actually a
2 legislative rule, you have to go through
3 notice-and-comment. So the government's --

4 JUSTICE BREYER: Well, yes, you know
5 that --

6 MR. SHAH: Yeah.

7 JUSTICE BREYER: -- and I know that.
8 But there are many, many people perhaps in the
9 United States, and including many who work in
10 agencies --

11 MR. SHAH: Well, Your Honor, the --

12 JUSTICE BREYER: -- who don't know
13 that. And so where it said in 1986 the word
14 "regulation," and then you read the House
15 report --

16 MR. SHAH: Yes.

17 JUSTICE BREYER: -- then we arrive at
18 the same conclusion that it already said it.

19 But many people don't read House
20 reports. And that word "regulation" might not
21 explain itself. And, therefore, they reenact
22 1987's law in order to put the House report, in
23 essence, in the law.

24 MR. SHAH: Well --

25 JUSTICE BREYER: And they show exactly

1 what they mean, okay?

2 MR. SHAH: Well, a --

3 JUSTICE BREYER: That's the argument
4 on the other side.

5 MR. SHAH: Well, a couple responses.
6 If you want to ignore the text and look at the
7 House report, I would suggest we look at the
8 1987 House report, which is the one that led to
9 Section (a)(2). And what it says there is we
10 tried this in 1986.

11 It turns out that the agency, and this
12 is a quote, "with growing frequency is enacting
13 significant" -- unquote -- is enacting
14 significant policies without going through not
15 -- notice-and-comment, notwithstanding our 1986
16 enactment. And, in fact, it -- the next
17 sentence says, in fact, it's doing these things
18 through things like manual instructions.

19 And so what we are going to do is
20 enact a further requirement that even if it is
21 a rule, whatever type, interpretive or
22 legislative, a requirement or a statement of
23 policy, as long as it's actually affecting a
24 standard changing effect on Medicare providers
25 or beneficiaries, their legal rights, then they

1 have to go through notice-and-comment.

2 And -- and let me point out, let's get
3 back to the fatal flaw, which the government
4 has still not addressed in its statutory
5 construction, other than saying that Congress's
6 use of the word "statement of policy" is an
7 artifact, that essentially Congress made a
8 mistake when they enacted the statute because
9 it didn't change -- it didn't strike everything
10 out except legislative rule.

11 The statute here says any rule,
12 requirement, or statement of policy. Now it's
13 not an artifact. A statement of policy -- this
14 is the government's construction -- only things
15 that have the force of law can have a standard
16 -- can affect a substantive legal standard.

17 Well, categorically, as the government
18 says on page 16 its reply brief, a statement of
19 policy under decades of APA law categorically
20 lacks the force of law.

21 So Congress has now enacted a statute
22 that says any rule, requirement, or statement
23 of policy can trigger notice-and-comment,
24 except you could never have a statement of
25 policy that triggers a notice of comment. Both

1 sides agree on that.

2 You are now reading significant words
3 out of a statute. That is not how statutory
4 construction works.

5 Now the government says: Oh, you
6 should just read this provision as simply
7 codifying the preexisting distinction between
8 substantive and interpretive rules in the APA,
9 the APA's interpretive rule exception.

10 Well, first of all, the term
11 "substantive legal standard" that they use in
12 (a)(2) appears nowhere in the APA or in any APA
13 cases. So it would be an exceedingly,
14 extraordinarily round-about way for Congress to
15 try to adopt the interpretive rule exception
16 which is sitting on the books, instead to
17 introduce new language which has never been
18 used in the APA to duplicate the interpretive
19 rule and section.

20 Instead of introducing that novel
21 concept, if all that's what the -- what
22 Congress wanted to do in (a)(2), it could have
23 simply cross-referenced the interpretive rule
24 exception in the APA, just like it
25 cross-referenced the neighboring good cause

1 exception, or it could have simply said any
2 substantive rule requires notice-and-comment.

3 That would have been a lot simpler.
4 And yet, obviously, Congress didn't do that.
5 It did almost the opposite. It -- it took --
6 it expressly includes any rule, requirement, or
7 statement of policy, which, if you compare it
8 to the interpretive rule exception in the APA,
9 that expressly carves out any interpretive rule
10 or statement of policy.

11 JUSTICE SOTOMAYOR: Could you give
12 meaning to legal, substantive legal?

13 MR. SHAH: Sure. So --

14 JUSTICE SOTOMAYOR: Because that --
15 that's where the strongest argument, I think
16 your adversary makes, which is generally we
17 think of legal as binding.

18 So, if you can deal with that, I think
19 --

20 MR. SHAH: Sure.

21 JUSTICE SOTOMAYOR: -- everything else
22 you're saying falls into place.

23 MR. SHAH: Sure. So substantive legal
24 standard, how we -- how we would view it is a
25 legal standard is, obviously, a term that's

1 used in law all the time. It's this legal
2 test, right?

3 And so, here, the legal standard in
4 their issuance is whether Part A entitled days
5 cover Part C days, whether they cover days that
6 are not covered under paid or covered under
7 Part A. So that's -- in substantive legal
8 standard, the legal standard is the test.

9 Here, we obviously have a test, that's
10 what the whole 2014 issuance is doing, defining
11 when Part C days are covered. So that's your
12 legal standard.

13 Now the question is, what work is
14 substantive doing? Well, then the work
15 substantive doing it, it's doing it in
16 contravention to procedural. And there is no
17 doubt here, everyone on both sides agree that
18 in that sense, substantive versus procedural,
19 what the agency did here has a substantive
20 effect. It's an effect towards billions of
21 dollars, it reduces the right of recovery or
22 reimbursement for these hospitals.

23 Now what the government says, they
24 point to this D.C. Circuit case called AHA v.
25 Bowen, and they say Congress made this change

1 in the statutory language and added the phrase
2 "substantive legal standard" to reflect that
3 ruling.

4 Well, first of all, when Congress made
5 that change, it said we are clarifying the
6 statute. It did not say we are doing a
7 wholesale change in the statute, which is what
8 the government's position is today at oral
9 argument. It said it's clarifying the statute.

10 Second point: That AHA v. Bowen case,
11 actually, substantive versus procedural is also
12 a distinction in the APA. There are
13 substantive rules, there are interpretive
14 rules, and there are procedural rules.

15 And what AHA v. Bowen says is
16 procedural rules, as opposed to substantive and
17 interpretive rules, also lack
18 notice-and-comment.

19 And it draws the distinction between
20 substantive and procedural. This is on pages
21 1045 to 1047 of AHA v. Bowen.

22 So even if we assume that Congress had
23 AHA v. Bowen in mind -- Congress is silent
24 about that in the House report -- but I'm
25 willing to take the government at face

1 value that --

2 JUSTICE KAGAN: Do you have any other
3 case that that might be when the conference
4 report says we're reflecting recent cases? Is
5 there anything else other than Bowen that you
6 think it might be referring to?

7 MR. SHAH: That -- that's the -- I
8 mean, we've looked. There really isn't
9 anything that's on point of the ones that we
10 could find in that time frame. Bowen is
11 obviously the one that the government focuses
12 on.

13 And we're happy to focus on that
14 because the core of Bowen is distinguishing a
15 procedural rule, things like enforcement
16 policies, auditing requirements on contractors,
17 how often you need -- the contractor has to go
18 and check the books of the hospital, those sort
19 of things.

20 It's distinguishing them from
21 substantive and interpretive rules. And so in
22 -- in -- if that's what Congress was trying to
23 do, that makes perfect sense. We agree that
24 (a)(2) excludes procedural rules from its
25 ambit.

1 It says any rule, requirement, or
2 statement of policy that alters a substantive
3 legal standard, so what's off the table are
4 like the rules in Clarion; things that have to
5 do with enforcement policies, enforcement
6 priorities, anything that's procedural in
7 nature is off the table.

8 So it's completely consistent.
9 Congress used words that make sense. They
10 departed from the APA. And it's completely
11 consistent with the legislative history.

12 Now, if I could --

13 JUSTICE BREYER: What about the
14 practical --

15 MR. SHAH: Yes.

16 JUSTICE BREYER: -- the practical?
17 And the reason is practical is relevant is you
18 make a very coherent argument for one view
19 that, at one time, the D.C. Circuit waffled
20 between that a legislative rule was an
21 important rule.

22 And the other side of it is, no, it
23 might or might not be. It is a legally binding
24 rule. That was Davis. And the D.C. Circuit
25 tried your approach but then went back.

1 And the reason was practical, that
2 once you start to say, as you're reading this
3 statute, that what they're talking about are
4 important rules, you see, and that's why they
5 put in not just rules but statements of policy,
6 et cetera. Once you do, you open the door to
7 agency after agency, and at least here with
8 this statute, saying what in heaven's name is
9 that?

10 You get into arguments about
11 everything, every word of a manual. And if
12 they avoid that by applying this statute, to
13 everything arguably important in every manual,
14 they will be here 'til Christmas come.

15 And -- and, moreover, they will have
16 to make decisions in advance that they really
17 don't understand until later.

18 And your client, so they might be
19 happy with this case, may not be so happy with
20 a few of the others that take 19 years to go
21 through -- I'm exaggerating --

22 MR. SHAH: Right.

23 MR. BREYER: -- but you see the
24 practical problem.

25 MR. SHAH: No. Yes.

1 JUSTICE BREYER: You don't see it or
2 you --

3 MR. SHAH: I do see your --

4 JUSTICE BREYER: That's why I want to
5 know the answer.

6 MR. SHAH: I see your concern.

7 JUSTICE BREYER: Yeah.

8 MR. SHAH: But here is why your
9 concern is misplaced here. And let me give you
10 three clear reasons why, and these -- these are
11 important.

12 First, we've already talked about the
13 Clarian decision. There's one D.C. Circuit
14 decision that actually applies the decision
15 here that they say is going to cause serious
16 problems for the administration of Medicare
17 Act.

18 The D.C. Circuit made clear they are
19 laying down a line, and that line is we're
20 going to take everything that has any anything
21 to do with enforcement priorities, auditing,
22 anything like that, so a large swath of
23 manual-type instructions, that was a manual
24 instruction in Clarian, off the table.

25 The second point, in its brief, the

1 government focuses on the provider
2 reimbursement manual. They say: Oh, virtually
3 all of this is going to require notice and
4 comment and -- and -- and raised some of the
5 concerns.

6 Well, the government still has not
7 provided a single example from that provider
8 reimbursement manual, so we took a look at that
9 provider reimbursement manual. It's about
10 6,000 pages long.

11 The last 5,000 pages of it are
12 procedural instructions on how to fill out the
13 cost reimbursement form. It's instructions to
14 providers. That's kind of like an exceedingly
15 complicated tax return.

16 And so the last 5,000 -- and, by the
17 way, of those last 5,000 pages, a lot of those
18 are obsolete because they don't pull out the
19 old instructions. It tells you to add line 20
20 to 21 to get to line 22. That means --

21 JUSTICE BREYER: But does the statute
22 apply only to provider manuals or does it
23 provide, say, let's say, to 320 or 240 million
24 Americans or 120 million Americans who get all
25 kinds of things from Medicare?

1 MR. SHAH: Well, Your Honor --

2 JUSTICE BREYER: And perhaps thousands
3 of hospitals and thousands of services. How
4 does -- if the statute's on just provider, you
5 have a good point, but is it?

6 MR. SHAH: Well, the problem that the
7 government points to are these manuals. And
8 what I'm telling you is the manuals --

9 JUSTICE BREYER: No, and I'm pointing
10 to a different problem.

11 MR. SHAH: Okay.

12 JUSTICE BREYER: I'm pointing to a
13 question --

14 MR. SHAH: So here --

15 JUSTICE BREYER: -- of whether this is
16 limited to provider manuals.

17 MR. SHAH: So here's -- here's --
18 well, it's limited to the terms of the statute.
19 It has to be a rule, requirement, or statement
20 of policy that changes or alters a substantive
21 legal standard affecting one of the three
22 categories of things. Right?

23 JUSTICE ALITO: Well, you explained
24 away the --

25 MR. SHAH: A right to payment --

1 JUSTICE ALITO: You -- you explained
2 away the last 5,000 pages of the manual.

3 MR. SHAH: Yes.

4 JUSTICE ALITO: But what about the
5 first thousand?

6 (Laughter.)

7 MR. SHAH: Okay. So the first -- the
8 first -- the remaining 980 pages, of that,
9 40 percent are from before 1987. (a)(2)'s
10 effective date applies to any manual --
11 anything promulgated after 1987. So that --
12 that's off the table. That leaves you your
13 roughly 400 pages, Justice Alito.

14 Of those, we went page by page through
15 those 400 pages. All of about 30 -- except for
16 about 35 of those pages, apply to the prior
17 cost reimbursement regime. That was the regime
18 of how Medicare used to do those things. And
19 those required detailed instructions.

20 Now, however, the vast, vast majority
21 of providers are governed by the prospective
22 payment system. Only about 35 pages apply to
23 those.

24 Now, even if 35 pages worth of stuff
25 needed to be done through notice-and-comment,

1 although I'm quite sure the government can come
2 up with all sorts of arguments why those 35
3 pages don't fall under (a)(2), but even if you
4 did -- and here, Justice Breyer, this should
5 address your concern better than anything I've
6 said so far.

7 There is an annual prospective payment
8 system rulemaking that the statute requires
9 when it made this change from reasonable cost
10 reimbursement to this new regime, to which
11 there are only 35 pages applicable.

12 That annual prospective payment
13 rulemaking is hundreds of pages long. And the
14 agency already puts everything governing
15 prospective payment systems that has a
16 substantive effect into that rulemaking.

17 In fact, 16 times before this case, it
18 adjusted the treatment of certain categories of
19 days through the prospective payment system
20 rulemaking.

21 JUSTICE BREYER: That's a prospective
22 payment manual, but read this.

23 MR. SHAH: This is not a manual.

24 JUSTICE BREYER: It says it governs
25 the scope of benefits.

1 MR. SHAH: Yes. And so --

2 JUSTICE BREYER: Not just -- and the
3 eligibility --

4 MR. SHAH: Right.

5 JUSTICE BREYER: -- of individuals to
6 furnish or receive services or benefits.

7 MR. SHAH: Right.

8 JUSTICE BREYER: So suddenly reading
9 that, I think it governs medicine and
10 healthcare provided 80 million people or 100
11 million people.

12 MR. SHAH: Sure. Well, Your Honor, a
13 couple responses.

14 JUSTICE BREYER: Am I right or wrong?

15 MR. SHAH: First of all -- first, it
16 would cover it if it falls under the terms of
17 the statute, but here is why that doesn't
18 create a workability problem. And not even the
19 government has argued that.

20 And here's why. First of all, all --
21 a lot of that stuff is already done through
22 rulemaking, just like the prospective payment
23 system rulemaking. That's one of many, many
24 annual rulemakings that the agency does,
25 hundreds of pages long, includes all of the

1 stuff that we have in here. There's no burden
2 to that.

3 And, by the way, those rulemakings
4 don't take 19 years, Justice Breyer. We went
5 through and averaged them. It's in the
6 appendix to our cert opposition brief. They
7 take on average 102 days to put through an
8 agency rulemaking on all of this stuff.

9 Now, to -- to address your other
10 question, a lot of that stuff is done through
11 regulation. A lot of that stuff, the stuff
12 that you're talking about, is this -- is this
13 drug or treatment covered to the thousands of
14 people who might submit a Medicare claim,
15 that's all done through national coverage
16 determinations, local determinations. And then
17 those are all adjudications.

18 There are thousands of those that are
19 done every day where the agency, a contractor
20 gets a Medicare claim. And that is just a
21 mine-run -- there is a reg -- there is a rule
22 on it. I apply the rule. Is this drug
23 covered? Yes or no.

24 JUSTICE SOTOMAYOR: Do you have any
25 idea --

1 MR. SHAH: That doesn't implicate
2 (a)(2).

3 JUSTICE SOTOMAYOR: Do you have any
4 idea why this change wasn't put through the
5 ordinary rulemaking notice and --

6 MR. SHAH: Yes, Your Honor, because
7 they tried. They did. In 2004, they did this
8 through notice-and-comment rulemaking or tried
9 to do it through notice --

10 JUSTICE SOTOMAYOR: I've now
11 forgotten. Why was that rebuffed?

12 MR. SHAH: Right. So --

13 JUSTICE SOTOMAYOR: I remember the
14 2013.

15 MR. SHAH: Yes.

16 JUSTICE SOTOMAYOR: But I don't
17 remember the --

18 MR. SHAH: Yes. So what happened is
19 they did the proposed rulemaking in 2003, which
20 said, look, we want to codify our long-standing
21 policy and practice of excluding Part C days
22 from the Medicare fraction. That's our
23 position as to how you should do this.

24 Then, in 2004, they did a 180-degree
25 turn but did not do any further

1 notice-and-comment, and they issued it as a
2 final rule to include the Part C days.

3 The D.C. Circuit in the precursor to
4 this case, what we call Allina I in the briefs,
5 said that's a logical outgrowth failure because
6 you've now flipped your long-standing policy
7 without any notice and comment.

8 So they tried to do it through
9 notice-and-comment, but because they got
10 rejected because of their defect in that
11 process, they then came to these -- they then
12 -- then they did the 2013 rulemaking, Justice
13 Sotomayor, that you're talking about, but, of
14 course, that's only going to apply
15 prospectively.

16 So then they were stuck while that
17 Allina I litigation was going on. Between 2005
18 to 2013, they had those years that were not
19 covered by their new rule, because that had
20 been invalidated for the logical outgrowth
21 failure, and was not covered by the 2013 rule,
22 which only operated prospectively.

23 So, rather than doing a proper
24 rulemaking, they simply announced these on a
25 website. They posted them on their website and

1 said: Now we are doing exactly the same thing
2 we were told that we tried to do in the 2004
3 final rule but was vacated by the D.C. Circuit.

4 So that's the answer.

5 CHIEF JUSTICE ROBERTS: Well, I guess
6 the way the government puts it is they decided
7 not to proceed through rulemaking but to
8 proceed through adjudication.

9 MR. SHAH: Well, Your Honor, as the
10 D.C. Circuit said, this looks nothing like an
11 adjudication. This policy that they introduced
12 on their website of including Part C days in
13 the Medicare fraction, that applies to every
14 hospital nationwide without exception. It has
15 prospective effect --

16 CHIEF JUSTICE ROBERTS: It's a big
17 adjudication.

18 MR. SHAH: Well -- well, I think what
19 distinguishes the adjudication from the
20 rulemaking is, does it have general
21 applicability? That's the definition in the
22 APA.

23 And this, as the D.C. Circuit said in
24 its opinion, and the fact is the government's
25 counsel in the D.C. Circuit oral argument

1 conceded, when asked at oral argument, doesn't
2 this policy have effect to every single
3 hospital in the nation -- nationwide, and the
4 answer is yes, it does.

5 And not only that, it's prospective
6 because these fractions are used, again, for
7 every hospital nationwide to calculate their
8 interim payments for the intervening year until
9 the new fractions come out.

10 CHIEF JUSTICE ROBERTS: Well, but --

11 MR. SHAH: So this looks nothing like
12 an adjudication.

13 CHIEF JUSTICE ROBERTS: -- if it is --
14 well, I guess, again, I mean, we can hear on
15 rebuttal, but, I mean, it's an adjudication
16 where they're doing what you'd like to see
17 people do in adjudication, which is apply the
18 same rules to similarly situated parties.

19 MR. SHAH: Well --

20 CHIEF JUSTICE ROBERTS: There just
21 happens to be a lot of them.

22 MR. SHAH: Right. Well -- well, that
23 -- that would be fine. But you can't issue a
24 -- a -- a policy that changes how you were
25 treating it and -- and have it have prospective

1 effect for every hospital nationwide without
2 complying with the terms of (a)(2), which says,
3 if you do any rule, requirement, or statement
4 of policy, you can't just give it a label that
5 says we're doing adjudication.

6 This has every effect of a rule,
7 requirement, or statement of policy in that
8 that treatment of Part C days, that is going to
9 decide the Medicare reimbursement amount, their
10 legal entitlement to reimbursement, for every
11 hospital nationwide.

12 CHIEF JUSTICE ROBERTS: So are --
13 you're saying this is not something that could
14 have been done through adjudication?

15 MR. SHAH: Well, Your Honor, not in
16 the way --

17 CHIEF JUSTICE ROBERTS: The -- the
18 agency could not choose adjudication as a means
19 of establishing this policy?

20 MR. SHAH: Not as a means of
21 establishing it nationwide for every hospital
22 nationwide. And the government has said that
23 when they would do these things, they apply the
24 same rule to each hospital.

25 So, no, if you're going to do

1 something like this, then -- you could call it
2 an adjudication. That's fine. But you have to
3 go through notice and comment when you're going
4 to be changing a substantive legal standard
5 that applies to them. And so they can't --
6 they can't now label this as adjudication.

7 Now, again, this is somewhat of a -- a
8 -- a -- of a theoretical question in this case,
9 because as the D.C. Circuit -- even the
10 district court, which ruled in front of the
11 government -- in favor of the government,
12 rejected their claim that this was an
13 adjudication and said this bears all the
14 hallmarks of a rule.

15 If there are no further questions, I'm
16 happy to sit down.

17 CHIEF JUSTICE ROBERTS: Thank you,
18 counsel.

19 Four minutes, Mr. Kneedler.

20 REBUTTAL ARGUMENT OF EDWIN S. KNEEDLER
21 ON BEHALF OF THE PETITIONER

22 MR. KNEEDLER: Several things,
23 Mr. Chief Justice.

24 Subsection (e), by the way, was
25 enacted at a later time, and so its text

1 doesn't necessarily shed light on what Congress
2 did in 1987.

3 The term "rule" in the lead-in to
4 subsection (a)(2) includes statements of
5 policy. So there's some redundancy or some --
6 it's superfluous there anyway, no matter -- no
7 matter how you read it. So it is -- it is
8 imprecise.

9 The conference committee report in
10 1987, I want -- I want to stress this, again
11 says recent court rulings. Those could only
12 have been APA rulings.

13 And, in fact, I -- I take my friend to
14 acknowledge that the American Hospital
15 Association case was the leading case, and that
16 case discussed the distinction between
17 substantive rules and both interpretive rules
18 and procedural rules, not just the one.

19 And as we point out on page 11 of our
20 reply brief, it did it in terms that are echoed
21 in the text of -- of hh itself. It says the
22 APA's notice-and-comment requirement applies
23 only to substantive rules that create law --
24 which goes to Justice Sotomayor's point about
25 what does "legal standard" mean -- creates law

1 and a -- "establish a standard of conduct"
2 which has the force of law. Those -- that
3 language is very close to what -- what is in
4 the statute as enacted.

5 This is really the last program in
6 which one would expect Congress to have created
7 such a transformation of administrative law as
8 Respondents are proposing here, that
9 interpretive rules, such as manuals -- and the
10 provider reimbursement manual is not the only
11 manual.

12 JUSTICE GORSUCH: But why -- why is
13 that? In *Chenery II*, this Court did allow the
14 government to engage in retroactive
15 adjudications that affect substantive rights,
16 but expected that it would be a rare thing that
17 that would happen and that most of these kinds
18 of actions would happen through rulemaking.

19 This, of course, is the Court's -- the
20 government's claiming the power to affect every
21 Medicare provider in the country retroactively
22 through these seriatim adjudications. Why is
23 -- why is this extraordinary?

24 MR. KNEEDLER: The Court addressed
25 that very situation in *Guernsey Memorial*

1 Hospital, in which it said some things can be
2 done by regulation, some things can be done by
3 manuals, and some things are done by
4 adjudication.

5 And the agency -- and this is the
6 teaching of Vermont Yankee, the agency has to
7 have the flexibility to choose. And this does
8 have the character of a -- of an adjudication,
9 going to the Chief Justice's question.

10 Yes, they sent it out to every
11 contractor performing on behalf of every
12 individual hospital, but that contractor's
13 determination for that -- for each of those
14 hospitals is an individual adjudication.

15 And the -- the application of this
16 fraction in that individual adjudication is not
17 binding. It -- it can be reversed on appeal to
18 the board or in court.

19 JUSTICE SOTOMAYOR: Can you point to
20 anything in the history of the '86 bill or '87
21 bill that leads substance to your claim that
22 Congress was not, in fact, concerned about
23 substantive changes in formulas like this one
24 being done through rulemaking as opposed to
25 adjudication?

1 MR. KNEEDLER: Well --

2 JUSTICE SOTOMAYOR: I thought in all
3 the history I read that was motivating them is
4 the agency's change of policy of doing less
5 than a rulemaking. They wanted more or the
6 same but not less.

7 CHIEF JUSTICE ROBERTS: You may.

8 MR. KNEEDLER: What Congress was
9 driving at -- and this comes from the word
10 "substantive," which has an established meaning
11 in administrative law and the APA -- was things
12 that have the force and effect of law, not
13 things that are simply interpretive. That's
14 the very distinction this Court drew in
15 Mortgage Bankers and in Guernsey Memorial
16 Hospital arising under this -- under this same
17 program.

18 CHIEF JUSTICE ROBERTS: Thank you,
19 counsel. The case is submitted.

20 (Whereupon, at 12:07 p.m., the case
21 was submitted.)

22

23

24

25

Official - Subject to Final Review

1	<p>above-entitled ^[1] 1:13</p> <p>accept ^[1] 36:22</p> <p>accepted ^[1] 5:22</p> <p>accomplishing ^[1] 24:2</p> <p>according ^[1] 32:22</p> <p>acknowledge ^[1] 61:14</p> <p>Act ^[1] 48:17</p> <p>action ^[1] 35:22</p> <p>actions ^[1] 62:18</p> <p>actually ^[6] 21:5 24:2 38:1 39:23 44:11 48:14</p> <p>add ^[1] 49:19</p> <p>added ^[1] 44:1</p> <p>address ^[4] 16:13 33:7 52:5 54:9</p> <p>addressed ^[2] 40:4 62:24</p> <p>adds ^[1] 6:12</p> <p>adjudicate ^[1] 35:24</p> <p>adjudication ^[20] 4:2 30:12 57:8, 11,17,19 58:12,15,17 59:5,14,18 60:2,6,13 63:4,8,14,16,25</p> <p>adjudications ^[3] 54:17 62:15,22</p> <p>adjusted ^[1] 52:18</p> <p>adjustment ^[3] 33:17 34:10,14</p> <p>administration ^[1] 48:16</p> <p>administrative ^[8] 3:19 22:10 25:4 33:22,24 35:19 62:7 64:11</p> <p>admit ^[1] 36:8</p> <p>adopt ^[2] 14:24 41:15</p> <p>adopts ^[1] 14:22</p> <p>advance ^[1] 47:16</p> <p>adversary ^[1] 42:16</p> <p>affect ^[3] 40:16 62:15,20</p> <p>affected ^[2] 30:15,22</p> <p>affecting ^[4] 11:20 14:3 39:23 50:21</p> <p>afraid ^[2] 31:16,17</p> <p>agencies ^[1] 38:10</p> <p>agency ^[29] 3:16,18 4:7,10,19 5:9, 10,14 9:11 14:13 22:12 23:22 27:19 31:3 33:16 35:4,6 36:25 39:11 43:19 47:7,7 52:14 53:24 54:8,19 59:18 63:5,6</p> <p>agency's ^[10] 4:5 6:4 16:23 32:5, 20,23 35:21,22,25 64:4</p> <p>agree ^[6] 12:22 22:6 25:9 41:1 43:17 45:23</p> <p>agreeing ^[2] 18:13 19:13</p> <p>AHA ^[5] 43:24 44:10,15,21,23</p> <p>aiming ^[1] 27:11</p> <p>AL ^[1] 1:7</p> <p>ALEX ^[1] 1:3</p> <p>ALITO ^[4] 50:23 51:1,4,13</p> <p>ALLINA ^[4] 1:7 3:5 56:4,17</p> <p>allow ^[1] 62:13</p> <p>almost ^[1] 42:5</p> <p>already ^[8] 13:2 24:5 26:16 37:19 38:18 48:12 52:14 53:21</p> <p>alter ^[1] 10:17</p> <p>altering ^[1] 10:18</p> <p>alternative ^[1] 30:19</p> <p>alters ^[2] 46:2 50:20</p> <p>although ^[1] 52:1</p> <p>ambit ^[1] 45:25</p> <p>amended ^[1] 7:20</p>	<p>amendment ^[1] 20:8</p> <p>American ^[2] 11:16 61:14</p> <p>Americans ^[2] 49:24,24</p> <p>amount ^[1] 59:9</p> <p>announce ^[1] 30:13</p> <p>announced ^[1] 56:24</p> <p>annual ^[3] 52:7,12 53:24</p> <p>answer ^[7] 9:22 12:3 17:3 28:18 48:5 57:4 58:4</p> <p>anyway ^[2] 20:19 61:6</p> <p>APA ^[36] 6:9,19,19,24 7:11,15 8:25 9:16 10:16 11:12 13:2,25 14:11, 18,22 15:1,12 17:9 21:15 25:4 27:5,8 31:23 37:21 40:19 41:8,12,12, 18,24 42:8 44:12 46:10 57:22 61:12 64:11</p> <p>APA's ^[3] 17:9 41:9 61:22</p> <p>appeal ^[8] 3:19 5:18,23 7:9 33:22, 25 35:19 63:17</p> <p>APPEARANCES ^[1] 1:17</p> <p>appears ^[1] 41:12</p> <p>appendix ^[1] 54:6</p> <p>applicability ^[1] 57:21</p> <p>applicable ^[1] 52:11</p> <p>application ^[1] 63:15</p> <p>applies ^[8] 15:10,12 30:13 48:14 51:10 57:13 60:5 61:22</p> <p>apply ^[7] 49:22 51:16,22 54:22 56:14 58:17 59:23</p> <p>applying ^[3] 3:24 29:15 47:12</p> <p>approach ^[1] 46:25</p> <p>area ^[2] 9:2 37:13</p> <p>Aren't ^[2] 17:7 37:7</p> <p>arguably ^[1] 47:13</p> <p>argued ^[1] 53:19</p> <p>argument ^[19] 1:14 2:2,5,8 3:4,7 12:11 21:7 32:14 36:14 37:10,17 39:3 42:15 44:9 46:18 57:25 58:1 60:20</p> <p>arguments ^[2] 47:10 52:2</p> <p>arising ^[1] 64:16</p> <p>around ^[3] 9:12,15 21:20</p> <p>arrive ^[1] 38:17</p> <p>articulation ^[1] 7:17</p> <p>artifact ^[3] 19:1 40:7,13</p> <p>aside ^[1] 7:8</p> <p>Association ^[2] 11:17 61:15</p> <p>assume ^[1] 44:22</p> <p>attention ^[1] 31:6</p> <p>auditing ^[2] 45:16 48:21</p> <p>authority ^[1] 35:23</p> <p>average ^[1] 54:7</p> <p>averaged ^[1] 54:5</p> <p>avoid ^[1] 47:12</p> <p>away ^[2] 50:24 51:2</p> <p>AZAR ^[2] 1:3 3:4</p>	<p>basis ^[1] 4:1</p> <p>bears ^[1] 60:13</p> <p>become ^[1] 4:8</p> <p>begin ^[1] 15:19</p> <p>behalf ^[11] 1:20,22 2:4,7,10 3:8 5:10 11:22 32:15 60:21 63:11</p> <p>behind ^[1] 35:23</p> <p>believe ^[3] 10:14 17:13,22</p> <p>beneficiaries ^[1] 39:25</p> <p>benefits ^[2] 52:25 53:6</p> <p>better ^[3] 22:12,12 52:5</p> <p>between ^[8] 6:9,25 11:25 41:7 44:19 46:20 56:17 61:16</p> <p>beyond ^[3] 18:3 25:11 37:13</p> <p>big ^[1] 57:16</p> <p>bill ^[10] 10:12,14,20 19:2 25:15,18, 20 34:21 63:20,21</p> <p>billions ^[2] 32:23 43:20</p> <p>bind ^[1] 14:13</p> <p>binding ^[18] 3:17 6:3 12:14,15 13:23 16:17 27:21 28:1,1 31:9 33:1,5, 8,19 35:14 42:17 46:23 63:17</p> <p>binds ^[1] 5:2</p> <p>bit ^[1] 25:9</p> <p>Black's ^[1] 25:6</p> <p>board ^[5] 4:3 35:21,25 36:16 63:18</p> <p>boards ^[1] 30:21</p> <p>boils ^[1] 13:20</p> <p>books ^[2] 41:16 45:18</p> <p>borrowing ^[1] 13:24</p> <p>both ^[5] 14:5 36:17 40:25 43:17 61:17</p> <p>bound ^[2] 7:4 35:21</p> <p>Bowen ^[8] 43:25 44:10,15,21,23 45:5,10,14</p> <p>BREYER ^[49] 8:21 9:10,21 12:3,20 13:14 19:22 21:16,19,23 22:2,15, 18,21,24 34:15 36:2,6,10,11,13,17, 22 37:12 38:4,7,12,17,25 39:3 46:13,16 47:23 48:1,4,7 49:21 50:2,9, 12,15 52:4,21,24 53:2,5,8,14 54:4</p> <p>brief ^[8] 8:6 9:18 11:16 25:7 40:18 48:25 54:6 61:20</p> <p>briefs ^[1] 56:4</p> <p>broad ^[2] 30:3 31:18</p> <p>broader ^[2] 6:19 24:15</p> <p>brought ^[1] 31:6</p> <p>burden ^[1] 54:1</p>
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