

# SUPREME COURT OF THE UNITED STATES

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IN THE SUPREME COURT OF THE UNITED STATES

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ALEX M. AZAR, II, SECRETARY )  
OF HEALTH AND HUMAN SERVICES, )  
Petitioner, )  
v. ) No. 17-1484  
ALLINA HEALTH SERVICES, ET AL., )  
Respondents. )  
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Pages: 1 through 64

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v. ) No. 17-1484

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Respondents. )

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

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

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

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

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

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

10 MR. KNEEDLER: So several points.

11 JUSTICE SOTOMAYOR: A statement of  
12 policy.

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

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

1 that binds what they're going to get.

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

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

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

11 When -- when the --

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

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

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

23 The grounds for that challenge might  
24 be different, but I can go into court and say  
25 it's ultra vires. I can go into court and say

1 it's not supported by the statute. It's not  
2 binding in -- in any meaningful way, other than  
3 that's what the agency's going to do.

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

9 And this Court in Guernsey --

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

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

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

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

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

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

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

12          MR. KNEEDLER: Well --

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

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

24                 But the conference report said this  
25 does not require notice-and-comment rulemaking



1 for interpretive rules or other things that are  
2 not now subject to that requirement.

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

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

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

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

25 Then Congress passes a statute and

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

8 MR. KNEEDLER: And that --

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

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

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

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

23 (Laughter.)

24 JUSTICE SOTOMAYOR: Well, the problem  
25 with -- with that --

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

3 JUSTICE SOTOMAYOR: -- counsel --

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

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

11 MR. KNEEDLER: The House bill.

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

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

21 MR. KNEEDLER: It -- it --

22 JUSTICE SOTOMAYOR: Because it tells  
23 me they are significantly concerned about  
24 things that make major changes, substantive  
25 changes in how people are being paid.

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

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

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

23          And the court there drew a sharp  
24          distinction between substantive rules on the  
25          one hand and interpretive and procedural rules

1 on the other hand.

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

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

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

16 That's what they're thinking about.  
17 And it's confused. And the 1987 statute  
18 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 8-2 says that any rule,  
16 requirement, or other statement of policy that  
17 establishes a substantive legal change has to  
18 go through informal rule-making, not even  
19 formal rule-making. And so really the question  
20 all boils down to what does "substantive" mean,  
21 I 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 your  
12 colleague on the other side that it is used in  
13 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 the  
9 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 to 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  
19 Court's 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 -- rule-making 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 rule-making 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  
9 treats them and say even faux statements of  
10 policy that are really rules and requirements  
11 and regulations, that's what it's aiming at.  
12 Isn't 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 rule-making a broad swath of what has never  
4 been 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 rule-making, not even formal rule-making,  
21 that's gone by the boards, but just informal  
22 notice and comment to affected parties in  
23 something as significant as changing the  
24 formula for Medicare for all Medicare providers  
25 nationwide, that maybe they should have 60 days

1 to at least throw in their comments.

2 MR. KNEEDLER: Well, first of all, the  
3 agency has tried to go through  
4 notice-and-comment rule-making 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: So, therefore, your  
7 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 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 court -- 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 it  
6 is 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. Now, that's basically their  
10 argument.

11 MR. SHAH: Right.

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

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 reports. And  
20 that word "regulation" might not explain  
21 itself.

22 And, therefore, they reenact 1987's  
23 law in order to put the House report in essence  
24 in the law.

25 MR. SHAH: Well --

1 JUSTICE BREYER: And they show exactly  
2 what they mean, okay?

3 MR. SHAH: Well, a --

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

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

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

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



1 or beneficiaries, their legal rights, then they  
2 have to go through notice-and-comment.

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

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

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

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

1 policy that triggers a notice of comment. Both  
2 sides agree on that.

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

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

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

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

1 cross-referenced the neighboring good cause  
2 exception or it could have simply said any  
3 substantive rule requires notice-and-comment.

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

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

14 MR. SHAH: Sure. So --

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

19 So if you can deal with that, I think  
20 --

21 MR. SHAH: Sure.

22 JUSTICE SOTOMAYOR: -- everything else  
23 you are saying falls into place.

24 MR. SHAH: Sure. So substantive legal  
25 standard, how we -- how we would view it is a

1 legal standard is, obviously, a term that's  
2 used in law all the time. It's this legal  
3 test, right?

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

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

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

24 Now what the government says, they  
25 point to this D.C. Circuit case called AHA v.

1 Bowen, and they say Congress made this change  
2 in the statutory language and added the phrase  
3 "substantive legal standard" to reflect that  
4 ruling.

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

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

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

20 And it draws the distinction between  
21 substantive and procedural. This is on pages  
22 1045 to 1047 of AHA v. Bowen.

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

1 willing to take the government at face  
2 value that --

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

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

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

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

1 ambit.

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

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

13 Now, if I could --

14 JUSTICE BREYER: What about the  
15 practical --

16 MR. SHAH: Yes.

17 JUSTICE BREYER: -- the practical?  
18 And the reason is practical is relevant is you  
19 make a very coherent argument for one view that  
20 at one time the D.C. Circuit waffled between  
21 that a legislative rule was an 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 are reading this  
3           statute, that what they are 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           it will be here till 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 --

22           MR. SHAH: Right.

23           MR. BREYER: I am exaggerating but you  
24           see the 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 your answer.

6 MR. SHAH: I see your concern, but  
7 here is why your concern is misplaced here.  
8 And let me give you three clear reasons why,  
9 and these are important.

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

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

23 The second point, in its brief the  
24 government focuses on the provider  
25 reimbursement manual. They say: Oh, virtually

1 all of this is going to require notice and  
2 comment and -- and -- and raised some of the  
3 concerns.

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

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

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

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

24 MR. SHAH: Well, Your Honor --

25 JUSTICE BREYER: And perhaps thousands

1 of hospitals and thousands of services. How  
2 does -- if the statute's on just provider, you  
3 have a good point, but is it?

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

7 JUSTICE BREYER: No, and I'm pointing  
8 to a different problem.

9 MR. SHAH: Okay.

10 JUSTICE BREYER: I'm pointing to a  
11 question --

12 MR. SHAH: So here --

13 JUSTICE BREYER: -- of whether this is  
14 limited to provider manuals.

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

21 JUSTICE ALITO: Well, You explained  
22 away the --

23 MR. SHAH: A right to payment --

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

1 MR. SHAH: Yes.

2 JUSTICE ALITO: But what about the  
3 first thousand?

4 (Laughter.)

5 MR. SHAH: The first -- the remaining  
6 980 pages, of that 40 percent are from before  
7 1987. The (a)(2)'s effective date applies to  
8 any manual -- anything promulgated after 1987.  
9 So that -- that's off the table. That leaves  
10 you your roughly 400 pages, Justice Alito.

11 Of those, we went page by page through  
12 those 400 pages. All of about 30 -- except for  
13 about 35 of those pages, apply to the prior  
14 cost reimbursement regime. That was the regime  
15 of how Medicare used to do those things.

16 And those required detailed  
17 instructions. Now, however, the vast, vast  
18 majority of providers are governed by the  
19 prospective payment system. Only about 35  
20 pages apply to those.

21 Now, even if 35 pages worth of stuff  
22 needed to be done through notice-and-comment,  
23 although I am quite sure the government can  
24 come up with all sorts of arguments why those  
25 35 pages don't fall under (a)(2), but even if

1 you did -- and here, Justice Breyer, this  
2 should address your concern better than  
3 anything I have said so far.

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

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

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

18           JUSTICE BREYER: That's a prospective  
19 payment manual, but read this.

20           MR. SHAH: It's not a manual.

21           JUSTICE BREYER: It says it governs  
22 the scope of benefits.

23           MR. SHAH: Yes. And so --

24           JUSTICE BREYER: And the  
25 eligibility --

1 MR. SHAH: Right.

2 JUSTICE BREYER: -- of individuals to  
3 furnish or receive services or benefits.

4 MR. SHAH: Right.

5 JUSTICE BREYER: So suddenly reading  
6 that, I think it governs medicine and  
7 healthcare provided 80 million people or 100  
8 million people.

9 MR. SHAH: Sure. Your Honor, a couple  
10 of responses.

11 JUSTICE BREYER: Am I right or wrong?

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

17 And here's why. First of all, all --  
18 a lot of that stuff is already done through  
19 rulemaking, just like the prospective payment  
20 system rulemaking. That's one of many, many  
21 annual rulemakings that the agency does,  
22 hundreds of pages long, includes all of the  
23 stuff that we have in here. There is no burden  
24 to that.

25 And, by the way, those rulemakings

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

6 Now, to -- to address your other  
7 question, a lot of that stuff is done through  
8 regulation. A lot of that stuff, the stuff  
9 that you are talking about, is this -- is this  
10 drug or treatment covered to the thousands of  
11 people who might submit a Medicare claim?

12 That's all done through national  
13 coverage determinations, local determinations.  
14 And then those are all adjudications.

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

20 JUSTICE SOTOMAYOR: Do you have any  
21 idea --

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

24 JUSTICE SOTOMAYOR: Do you have any  
25 idea why this change wasn't put through the

1 ordinary rulemaking notice in --

2 MR. SHAH: Yes, Your Honor, because  
3 they tried. They did. In 2004, they did this  
4 through notice-and-comment rulemaking or tried  
5 to do it.

6 JUSTICE SOTOMAYOR: I've now  
7 forgotten. Why was that rebuffed?

8 MR. SHAH: Right. So --

9 JUSTICE SOTOMAYOR: I remember the  
10 2013 --

11 MR. SHAH: Yes.

12 JUSTICE SOTOMAYOR: But I don't  
13 remember the --

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

20 Then in 2004, they did a 180-degree  
21 turn, but did not do any further  
22 notice-and-comment. And they issued it as a  
23 final rule to include the Part C days.

24 The D.C. Circuit in the precursor to  
25 this case, what we call Allina I in the briefs,



1 said that's a logical outgrowth failure because  
2 you have now flipped your long-standing policy  
3 without any notice and comment.

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

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

19 So rather than doing a proper  
20 rulemaking, they simply announced these on a  
21 web site. They posted them on their web site  
22 and said: Now we are doing exactly the same  
23 thing we were told that we tried to do in the  
24 2004 final rule, but was vacated by the D.C.  
25 Circuit.

1                   So that's the answer.

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

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

13                   CHIEF JUSTICE ROBERTS: It's a big  
14 adjudication.

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

20                   And this, as the D.C. Circuit said in  
21 its opinion, and the fact is the government's  
22 counsel in the D.C. Circuit oral argument  
23 conceded, when asked at oral argument, doesn't  
24 this policy have effect to every single  
25 hospital in the nation -- nationwide? And the

1 answer is yes, it does.

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

7 CHIEF JUSTICE ROBERTS: Well, but --

8 MR. SHAH: So, this looks nothing like  
9 an adjudication.

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

16 MR. SHAH: Well --

17 CHIEF JUSTICE ROBERTS: There just  
18 happens to be a lot of them.

19 MR. SHAH: Right. Well -- well, that  
20 -- that would be fine. But you can't issue a  
21 -- a -- a policy that changes how you were  
22 treating it and -- and have it have prospective  
23 effect for every hospital nationwide without  
24 complying with the terms of (a)(2), which says  
25 if you do any rule, requirement, or statement

1 of policy, you can't just give it a label that  
2 says we're doing adjudication.

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

9 CHIEF JUSTICE ROBERTS: So are --  
10 you're saying this is not something that could  
11 have been done through adjudication?

12 MR. SHAH: Well, Your Honor, not in  
13 the way --

14 CHIEF JUSTICE ROBERTS: The -- the  
15 agency could not choose adjudication as a means  
16 of establishing this policy?

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

22 So, no, if you're going to do  
23 something like this, then -- you could call it  
24 an adjudication. That's fine. But you have to  
25 go through notice and comment when you're going

1 to be changing a substantive legal standard  
2 that applies to them. And so they can't --  
3 they can't now label this as adjudication.

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

12 If there are no further questions, I'm  
13 happy to sit down.

14 CHIEF JUSTICE ROBERTS: Thank you,  
15 counsel.

16 Four minutes, Mr. Kneedler.

17 REBUTTAL ARGUMENT OF EDWIN S. KNEEDLER  
18 ON BEHALF OF THE PETITIONER

19 MR. KNEEDLER: Several things,  
20 Mr. Chief Justice:

21 Subsection (e), by the way, was  
22 enacted at a later time, and so its text  
23 doesn't necessarily shed light on what Congress  
24 did in 1987.

25 The term "rule" in the lead-in to

1 subsection (a)(2) includes statements of  
2 policy. So there is some redundancy or some --  
3 it's superfluous there anyway, no matter -- no  
4 matter how you read it. So it is -- it is  
5 imprecise.

6 The conference committee report in  
7 1987, I want -- I want to stress this, again  
8 says recent court rulings. Those could only  
9 have been APA rulings.

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

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

1 the statute as enacted.

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

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

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

21 MR. KNEEDLER: The Court addressed  
22 that very situation in *Guernsey Memorial*  
23 *Hospital*, in which it said some things can be  
24 done by regulation, some things can be done by  
25 manuals, and some things are done by

1 adjudication.

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

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

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

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

23 MR. KNEEDLER: Well --

24 JUSTICE SOTOMAYOR: I thought in all  
25 the history I read that was motivating them is



1 the agency's change of policy of doing less  
2 than rulemaking. They wanted more or the same  
3 but not less.

4 CHIEF JUSTICE ROBERTS: You may.

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

15 CHIEF JUSTICE ROBERTS: Thank you,  
16 counsel. The case is submitted.

17 (Whereupon, at 12:07 p.m., the case  
18 was submitted.)

19  
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