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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 412**

**[CMS-1739-F]**

**RIN 0938-AU24**

# Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Final action.

**SUMMARY:** This final action establishes a policy concerning the treatment of patient days associated with persons enrolled in a Medicare Part C (also known as "Medicare Advantage") plan for purposes of calculating a hospital's disproportionate patient percentage for cost reporting periods starting before fiscal year (FY) 2014 in response to the Supreme Court's ruling in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (June 3, 2019).

**DATES**: The policy set out in this final action is effective [Insert date 60 days after the date of publication in the **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Donald Thompson, DAC@cms.hhs.gov, (410) 786-4487.

**SUPPLEMENTARY INFORMATION:**

## I. Executive Summary and Background

### A. Executive Summary

#### 1. Purpose and Legal Authority

This final action creates a policy governing the treatment of days associated with beneficiaries enrolled in Medicare Part C for discharges occurring prior to October 1, 2013, for

the purpose of determining the additional Medicare payments to subsection (d) hospitals under section 1886(d)(5)(F) of the Social Security Act (the Act).

2. Summary of Major Provisions

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) payment adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the "Pickle method." The second method for qualifying for the DSH payment adjustment, which is more common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction." The Medicare fraction (also known as the SSI fraction or SSI ratio) is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the hospital inpatient prospective payment system (IPPS) for acute care hospitals, the statutory references to "days" in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days.

Regulations located at 42 CFR 412.106 implement the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment.

3. Summary of Costs and Benefits

Including days associated with patients enrolled in Medicare Part C in the calculation of the Medicare fraction and excluding them from the calculation of the numerator of the Medicaid fraction, does not have any additional costs or benefits relative to the Medicare DSH payments that have already been made because those payments were made under the policy reflected in the fiscal year (FY) 2005 IPPS final rule (69 FR 49099) (prior to it having been vacated). The effect of this final action is to provide certainty as to how Part C days will be treated for DSH calculations for cost years not governed by the FY 2014 IPPS/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (78 FR 50614; hereinafter referred to as "the FY 2014 IPPS final rule"), resolving any uncertainty that may otherwise continue into the future.

B. Background

In August 2020, we issued a proposed rule, which appeared in the **Federal Register** on August 6, 2020 (85 FR 47723) (hereinafter referred to as the "August 2020 proposed rule"). The proposed rule would establish a policy concerning the treatment of patient days associated with persons enrolled in a Medicare Part C (also known as "Medicare Advantage" or "MA") plan for purposes of calculating a hospital's disproportionate patient percentage for cost reporting periods starting before October 1, 2013, in response to the Supreme Court's ruling in *Azar v. Allina Health Services*.

We received approximately 110 timely pieces of correspondence containing multiple comments on the August 2020 proposed rule. Summaries of the public comments received and our responses to those public comments are set forth in section II. of this final action.

**II. Provisions of the Regulations--Treatment of Patient Days Associated with Patients Enrolled in Medicare Advantage Plans with Discharge Dates Before October 1, 2013, in the Medicare and Medicaid Fractions of the Disproportionate Patient Percentage (DPP)**

Medicare Advantage (MA) plans are authorized under Medicare Part C. The regulation at 42 CFR 422.2 defines MA plan to mean "health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan . . . ." Generally, each MA plan must at least provide coverage of all services that are covered by Medicare Part A and Part B, but also may provide for Medicare Part D benefits and/or additional supplemental benefits. However, certain items and services, such as hospice benefits, continue to be covered under Medicare Part A fee-for-service (FFS) even if a beneficiary chooses to enroll in an MA plan. Generally, under § 422.50 of the regulations, an individual is eligible to elect an MA plan if he or she is entitled to Medicare Part A and enrolled in Medicare Part B. This is in accordance with section 1851(a)(3) of the Act, which requires that individuals enrolling in MA plans must be entitled to benefits under Part A and enrolled under Part B. Dually eligible beneficiaries (individuals entitled to Medicare and eligible for Medicaid) may choose to enroll in an MA plan.

In the FY 2004 IPPS proposed rule (68 FR 27208), in response to questions about whether the patient days associated with patients enrolled in an MA plan should be counted in the Medicare fraction or the Medicaid fraction of the DPP calculation, we proposed that once a beneficiary enrolls in an MA plan, patient days attributable to the beneficiary would not be included in the Medicare fraction of the DPP. (We note, at the time of the FY 2004 IPPS proposed rule and FY 2005 rulemaking, Medicare Part C was referred to as Medicare + Choice (M+C); however, to avoid confusion we use the current terminology (MA) when referring to Medicare Part C.) Instead, those patient days would be included in the numerator of the Medicaid fraction, if the patient also were eligible for Medicaid. In the FY 2004 IPPS final rule

(68 FR 45422), we did not respond to public comments on this proposal, due to the volume and nature of the public comments we received, and we indicated that we would address those comments later in a separate document. In the FY 2005 IPPS proposed rule (69 FR 28286), we stated that we planned to address the FY 2004 comments regarding MA days in the IPPS final rule for FY 2005. After considering comments on this proposal, we decided not to implement the policy as proposed. Instead, in the FY 2005 IPPS final rule (69 FR 49099; hereinafter referred to as "the FY 2005 IPPS final rule"), we determined that, under § 412.106(b)(2)(i) of the regulations, MA patient days should be counted in the Medicare fraction of the DPP calculation. We explained that, even where Medicare beneficiaries enroll in an MA plan, they are still entitled to benefits under Medicare Part A. Therefore, we noted that if an MA beneficiary is also entitled to SSI benefits, the patient days for that beneficiary would be included in the numerator of the Medicare fraction (as well as in the denominator) and not in the numerator of the Medicaid fraction. We note that, despite our statement in the FY 2005 IPPS final rule that the text of the regulation at § 412.106(b)(2)(i) would be revised to state explicitly that the days associated with MA beneficiaries are included in the Medicare fraction, due to a clerical oversight, the regulation at § 412.106(b)(2)(i) was not amended to reflect this policy until 2007 (72 FR 47384).

In 2012, a district court vacated the final policy adopted in the FY 2005 IPPS final rule on the basis that the final rule was not a "logical outgrowth" of the proposed rule. *Allina Health Svcs. v. Sebelius*, 904 F. Supp. 2d 75, 89 (D.D.C. 2012). In the FY 2014 IPPS/LTCH PPS proposed rule (hereinafter referred to as "the FY 2014 IPPS proposed rule"), we proposed to re-adopt the policy of including MA patient days in the Medicare fraction prospectively for FY 2014 and subsequent fiscal years (78 FR 27578). We finalized this proposal in the FY 2014 IPPS final rule (78 FR 50614). We made no change to the regulation text at § 412.106(b)(2)(i) because the text of the regulation which was revised in 2007 (72 FR 47384) to incorporate the policy we first adopted in the FY 2005 IPPS final rule, already reflected the policy we again adopted in the FY 2014 IPPS final rule. In 2014, the United States Court of Appeals for the D.C.

Circuit upheld the district court's holding that the policy adopted in the FY 2005 IPPS final rule requiring inclusion of Part C days in the Medicare fraction was not a logical outgrowth of the proposed rule, but left open the possibility that the agency could treat Part C days the same way through adjudication.

In *Azar v. Allina Health Services*, 139 S. Ct. 1804 (June 3, 2019, hereinafter referred to as *Allina II*), the Supreme Court considered a challenge to the agency's inclusion of MA patient days in the Medicare fractions it published for FY 2012. Section 1871(a)(2) of the Act requires notice-and-comment rulemaking for any Medicare "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits." The Supreme Court held that section 1871(a)(2) of the Act required CMS to engage in notice-and-comment rulemaking before adopting its "avowedly gap-filling policy" regarding treatment of inpatient days for beneficiaries enrolled in MA plans for purposes of calculating the DPP.

Section 1871(e)(1)(A) of the Act authorizes CMS to engage in retroactive rulemaking when the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that a failure to apply a policy retroactively would be contrary to the public interest. For example, CMS has invoked its authority to engage in retroactive rulemaking under section 1871(e)(1)(A) of the Act in connection with its policy related to bad debt (see the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32867)), predicate facts and cost report reopening (see the CY 2014 OPPS final rule (78 FR 75165)), and the low-volume hospital adjustment (see the FY 2020 IPPS/LTCH PPS final rule (84 FR 42349)).

The Secretary has determined that to the extent there is a statutory gap to fill with respect to the treatment of Part C patient days, retroactive application is necessary to comply with statutory requirements and a failure to apply this policy retroactively would be contrary to the public interest. Section 1886(d)(5)(F) of the Act requires CMS to make DSH payments to

eligible hospitals. Calculating such payments, in turn, requires CMS to calculate a Medicare fraction and a Medicaid fraction for each hospital. Under section 1886(d)(5)(F)(vi)(I) of the Act, the Medicare fraction must include the patient days for beneficiaries "entitled to benefits under part A." The Court of Appeals for the D.C. Circuit has held that the Medicare statute does not speak directly to how Part C days should be treated for purposes of DSH calculations, that is, whether Part C patients are "entitled to benefits under part A" and should therefore be included in the Medicare fraction, or whether they are not so entitled, and should therefore be included in the numerator of the Medicaid fraction if they are also eligible for Medicaid. (See *Northeast Hospital Corporation v. Sebelius*, 657 F.3d 1, 13 (D.C. Cir. 2011) (hereinafter referred to as "*Northeast*".) However, the court has also found that section 1886(d)(5)(F)(vi) of the Act requires the Secretary to account for Part C days in the DPP calculation by including them in one of the fractions (Medicare or Medicaid) and excluding them from the other. (See *Allina Health Services. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (hereinafter referred to as "*Allina I*").)

Since the publication of our proposed rule, the Supreme Court handed down its decision in *Becerra v. Empire Health Foundation,* 142 S. Ct. 2354, 1368 (June 24, 2022) (hereinafter referred to as "*Empire*"). In *Empire*, the Supreme Court held that the statutory text is clear that "being 'entitled' to Medicare benefits . . . means – in the [DSH] fraction descriptions, as throughout the statute – meeting the basic statutory criteria." (142 S. Ct. at 2362.) Part C enrollees, who by definition must be "entitled" to Part A benefits to enroll under Part C, necessarily meet the basic statutory criteria (essentially that they are over 65 or disabled). *Empire* did not address Part C days specifically, it addressed the same statutory language that is the subject of the August 2020 proposed rule, the meaning of "entitled to benefits under part A of [Medicare]." The Supreme Court held that the Secretary was correct in interpreting that phrase as denoting a legal status that does not turn on whether Medicare pays for any particular hospital day. The Supreme Court concluded that the "[t]ext, context, and structure all support calculating

the Medicare fraction HHS's way. In that fraction, individuals 'entitled to [Medicare Part A] benefits' are all those qualifying for the program." We believe it is now clear that the statute itself requires the Secretary to count Part C days in the Medicare fraction because Medicare beneficiaries remain "entitled to [Medicare Part A]" regardless of whether they enroll in Part C, just as do beneficiaries who have exhausted their coverage for a spell of illness. Nonetheless, *Empire* did not address specifically whether Part C enrollees remain "entitled to Part A," and because the FY 2005 IPPS final rule was vacated, the Secretary "has no promulgated rule governing" the treatment of Part C days "for the fiscal years before 2014." *Allina Health Servs. v. Price*, 863 F.3d 937, 939 (D.C. Cir. 2017). As a result, to the extent there is still a statutory gap for the Secretary to fill after *Empire* regarding the treatment of Part C days in the Medicare DSH payment calculation, CMS must determine whether beneficiaries enrolled in Part C are "entitled to benefits under part A" and so must be included in the Medicare fraction (and excluded from the numerator of the Medicaid fraction), or are not so entitled and so must be excluded from the Medicare fraction (and included in the numerator of the Medicaid fraction, if dually eligible). The Secretary has therefore determined that, in order to comply with the statutory requirement to make DSH payments and in order to address any potential statutory gap, to the extent one might remain after *Empire*, it is necessary for CMS to engage in retroactive rulemaking to establish a policy to govern whether individuals enrolled in MA plans should be included in the Medicare fraction or in the numerator of the Medicaid fraction, if dually eligible, for fiscal years before 2014.

We continue to believe, as we stated in the preamble to the FY 2014 IPPS final rule (78 FR 50614 and 50615) and have consistently expressed since the issuance of the FY 2005 IPPS final rule, that individuals enrolled in MA plans are "entitled to benefits under part A" as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi) of the Act. Even without relying on the Supreme Court's decision in *Empire*, which in our view confirms our interpretation, we believe this is the best reading of the statute.

Section 226 of the Act provides that an individual is automatically "entitled" to Medicare Part A when the person reaches age 65, provided that the individual is entitled to Social Security benefits under section 202 of the Act, or becomes disabled. Beneficiaries who are enrolled in MA plans provided under Medicare Part C continue to meet all of the statutory criteria for entitlement to Medicare Part A benefits under section 226 of the Act. Moreover, section 1851(a)(3) of the Act provides that in order to enroll in Medicare Part C a beneficiary must be "entitled to benefits under Part A and enrolled under Part B." Thus, by definition, a beneficiary must be entitled to Part A to be enrolled in Part C. There is nothing in the Act that suggests that beneficiaries who enroll in a Medicare Part C plan thereby forfeit their entitlement to Medicare Part A benefits. To the contrary, enrollment in a plan under Medicare Part C is simply an option that a person entitled to Part A benefits may choose as a way to receive their Part A benefits. A beneficiary who enrolls in Medicare Part C is entitled to receive benefits under Medicare Part A through the MA plan in which he or she is enrolled, and the MA organization's costs in providing such Part A benefits are paid for by CMS with money from the Medicare Part A Trust Fund. In addition, under certain circumstances, Medicare Part A pays directly for care furnished to patients enrolled in Medicare Part C plans, rather than indirectly through Medicare Part A Trust Fund payments to MA organizations. For example, under section 1852(a)(5) of the Act, if, during the course of the year, the scope of benefits provided under Medicare Part A expands beyond a certain cost threshold due to congressional action or a national coverage determination, Medicare Part A will pay providers directly for the cost of those services provided to beneficiaries enrolled in Part C. Similarly, Medicare Part A pays directly for hospice care furnished to MA patients who elect under section 1812(d)(1) of the Act to receive such care from a particular hospice program and, under certain circumstances, for federally qualified health center (FQHC) services provided to MA patients by FQHCs that contract with MA organizations under sections 1853(h)(2) and 1853(a)(4) of the Act, respectively. Thus, we continue to believe that a patient enrolled in an MA plan remains entitled to benefits under Medicare Part A, and

patient days associated with that patient should be counted in the Medicare fraction of the DPP, and not (in the case of a dually-eligible patient) the numerator of the Medicaid fraction.

Additionally, the Secretary has determined that it is in the public interest for CMS to adopt a retroactive policy for the treatment of MA patient days in the Medicare and Medicaid fractions through notice and comment rulemaking for discharges before October 1, 2013 (the effective date of the FY 2014 IPPS final rule). CMS must calculate DSH payments for periods that include discharges occurring before the effective date of the prospective FY 2014 IPPS final rule for hundreds of hospitals whose DSH payments for those periods are still open or have not yet been finally settled, encompassing thousands of cost reports. In order to calculate these payments, CMS must establish Medicare fractions for each applicable cost reporting period during the time period for which there is currently no regulation in place that expressly addresses the treatment of Part C days. Because the Supreme Court has held in *Allina II* that, unless an exception applies, CMS cannot establish or change "an avowedly 'gap'-filling policy" under the Medicare statute except by notice-and-comment rulemaking, we have concluded that, to the extent there is a gap after *Empire*, the only way for CMS to resolve this issue and properly calculate DSH payments for time periods before FY 2014 is to promulgate a new regulation through notice-and-comment rulemaking that would apply retroactively to the determination of Medicare and Medicaid fractions for this time period. Consequently, retroactive rulemaking is not only necessary to comply with the statutory requirement to calculate DSH payments, it is also necessary to avoid an outcome that would be contrary to the public interest. Absent such a retroactive rulemaking, if there is a gap in the statute to fill, the Secretary would be unable to calculate and confirm proper DSH payments for time periods before FY 2014, which would be contrary to the public interest of providing additional payments to hospitals that serve a significantly disproportionate number of low-income patients, as expressed in the DSH provisions of the Medicare statute. Moreover, to the extent the Secretary must adopt an approach to calculate those payments, it is in the public interest to permit interested stakeholders

to comment on the proposed approach and for the agency to have the benefit of those comments in the development of any final action. Therefore, for the purposes of calculating the Medicare and Medicaid fractions for cost reporting periods that include discharges before October 1, 2013, in the August 2020 proposed rule (85 FR 47725), we proposed to adopt the same policy of including MA patient days in the Medicare fraction that was prospectively adopted in the FY 2014 IPPS final rule and to apply this policy retroactively to any cost reports that remain open for cost reporting periods starting before October 1, 2013. We stated that we did not expect the proposed policy to have an effect on payments as the payments previously made already reflect the proposed policy. We did not propose any change to the regulation text because the current text at § 412.106(b)(2)(i) reflects the policy being proposed for fiscal years before FY 2014. In the August 2020 proposed rule (85 FR 47726), we stated that because we proposed to establish this policy retroactively, it would cover cost reporting periods for which many cost reports have already been final settled. Consistent with 42 CFR 405.1885(c)(2), any final action retroactively adopting the policy at 42 CFR 412.106(b)(2)(i) for fiscal years before FY 2014 would not be a basis for reopening these final settled cost reports, irrespective of how payments in those cost reports were calculated.

In the August 2020 proposed rule, we sought comments on our proposed approach to include MA patient days in the Medicare fraction for fiscal years before FY 2014, and also on an alternative, of including MA patient days for dually eligible beneficiaries in the numerator of the Medicaid fraction for those fiscal years, which we discussed in detail in section V. of the August 2020 proposed rule (85 FR 47727). We summarize and respond to the public comments received on our proposal and the alternative approach considered in the proposed rule.

*Comment*: Some commenters stated that the statute unambiguously forecloses the Secretary's interpretation and is self-executing, so retroactive rulemaking cannot be justified.

*Response*: We disagree that the statute unambiguously forecloses the Secretary's interpretation. Quite the opposite is true; based on the Supreme Court's intervening decision in

*Empire*, we believe the statute itself requires the Secretary to count Part C days in the Medicare fraction, exactly as contemplated in the August 2020 proposed rule. To the extent that the statute itself establishes the applicable "substantive legal standard," there is no need for a "gap-filling policy" that would trigger the notice-and-comment obligations of section 1871(a)(2) of the Act, nor any resulting need to rely on the retroactive rulemaking authority under section 1871(e) of the Act. The Supreme Court in *Allina II* made clear that while notice-and-comment rulemaking is required to change or establish an "avowedly 'gap'-filling policy," its holding should not be construed to require such rulemaking where the substantive legal standard is established by the statute itself. (139 S. Ct. at 1816-17.) Of course, to the extent notice-and-comment rulemaking is required under *Allina II*, we continue to believe that this final action is a necessary and appropriate exercise of the Secretary's retroactive rulemaking authority under section 1871(e) of the Act. In our view, however, *Empire* now makes clear that the interpretation set forth in this final action simply reflects the "substantive legal standard" already set forth in the statute and the action thus does not "establish or change" that standard.

Although *Empire* did not address Part C days specifically, it addressed the same statutory language at issue here, and its analysis of that language compels the conclusion that Part C days must be treated as days for which patients are "entitled to part A benefits." Under the governing statutory language, patients are "entitled" to Part A benefits if they meet the basic statutory criteria for such entitlement under section 226 of the Act—essentially, if they are over 65 or disabled. (142 S. Ct. at 2358, 2361-62, 2365-66.) As noted previously, Part C enrollees must, by definition, meet these statutory criteria. And because their enrollment in MA does not change their age or disability status, such enrollment also does not change their entitlement to benefits under Part A.[1] There is no indication in the *Empire* Court's opinion to suggest that some other interpretation might be permissible. To the contrary, the Court held that the meaning of the

[1] 142 S. Ct. at 2364 (explaining that "entitlement" arises when a person meets the basic criteria and, unless a disability diminishes, "never goes away").

statute was clear (indeed, "surprisingly clear"), and that the Secretary had "correctly" interpreted the statutory language.[2] It also held that the alternative reading (including the reading advanced by the plaintiffs in *Northeast*, a Part C days case) would render various statutory provisions "unworkable or unthinkable or both," which "is not the statute Congress wrote."[3] It further found that excluding Medicare beneficiaries from the Medicare fraction denominator simply because payment was not made under Medicare Part A would "deflate" the Medicare fraction denominator and "distort[] what the Medicare fraction is designed to measure—the share of low-income Medicare patients relative to the total."[4] The same concern applies at least as much, if not more, in the context of Part C days.

In short, based on the *Empire* Court's clarification of the governing statute, we now believe the interpretation announced here simply reflects the substantive legal standard already established in "the statute Congress wrote," and that this action itself does not establish or change that standard.[5] That being the case, we now believe that notice-and-comment rulemaking is not required under *Allina II*, and the interpretation set forth in this action is proper without a need to rely on the Secretary's retroactive rulemaking authority.

Alternatively, if notice-and-comment rulemaking is required, then we continue to believe this action reflects an appropriate exercise of the Secretary's retroactive rulemaking authority. The commenters are incorrect to say the statute unambiguously forecloses the Secretary's interpretation. Even before the Supreme Court in *Empire* found that the Secretary had correctly construed the statutory language, the D.C. Circuit in *Northeast* held that "the statute does not unambiguously foreclose the Secretary's interpretation."[6] The D.C. Circuit found that Congress "left a statutory gap, and it is for the Secretary . . . to fill that gap."[7] Thus, to the extent that any such gap remains in the wake of the Supreme Court's clarification in *Empire*, the decision in

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[2] *Id.* at 2362.
[3] *Id.* at 2364.
[4] *Id.* at 2367-68.
[5] 142 S. Ct. at 2364.
[6] 657 F.3d at 2.
[7] *Id.* at 13.

*Allina II* would require notice-and-comment rulemaking to establish the gap-filling policy stated in this action.[8]

*Comment*: Several commenters stated that retroactive rulemaking in this context offends "fundamental notions of justice" and the public interest and sets a dangerous precedent by giving CMS a way to evade the notice-and-comment requirements of the Medicare statute and the Administrative Procedure Act (APA) whenever it loses a procedural challenge in court. Some stated that retroactive rulemaking subverts what the Supreme Court in *Allina II* identified as Congress' purpose in the notice-and-comment requirement—giving the public fair warning and a chance to be heard. Some commenters suggested that it is poor public policy and contrary to the public interest to finalize a retroactive rule when the earlier rulemaking was found deficient on logical outgrowth grounds. A commenter stated that CMS's proposal suggests that there are no practical consequences associated with the agency's failure to comply with the APA.

*Response*: To the extent that *Empire* has now held that our interpretation of the statute reflects its clear meaning, we need not rely on retroactive rulemaking authority, as discussed previously. But to the extent retroactive rulemaking is necessary, we do not agree that retroactive rulemaking here offends justice, sets a dangerous precedent, or evades the APA's notice-and-comment rulemaking requirement. As described in the August 2020 proposed rule and herein, this retroactive rulemaking is authorized by statute, specifically section 1871(e) of the Act, complies with the Medicare statute's notice-and-comment requirement, and implements the Supreme Court's decision in *Allina II*, thereby upholding fundamental notions of justice. The Supreme Court did not expressly instruct CMS to promulgate a retroactive rule, but it did hold that the Medicare statute requires the agency to engage in notice-and-comment rulemaking before it may either "establish" or "change" a substantive legal standard, such as its policy governing the treatment of Part C days in the DSH statute, if such a policy is intended to fill a statutory gap. As noted previously, because the FY 2005 IPPS final rule was vacated, no policy

[8] 139 S. Ct. at 1816-17.

governing the treatment of Part C days has been established by rulemaking for fiscal years before 2014. Thus, for fiscal years not already addressed by the FY 2014 IPPS final rule,[9] whether CMS interprets the statute to treat beneficiaries enrolled in Part C as "entitled to benefits under part A" or as not so entitled, the Medicare statute requires a policy established by notice-and-comment rulemaking to resolve the issue for these years, at least to the extent that any statutory "gap" remains to be filled after *Empire*. If CMS were to proceed to calculate DSH adjustments for fiscal years before 2014 without a promulgated rule in place, this would (to the extent any gap remains) be contrary to the holding of *Allina II* because the Supreme Court held that gaps in the Medicare statute can only be filled via rulemaking (unless an exception applies). The *Allina II* plaintiffs prevailed only on their procedural challenge. No provision of either the Medicare statute or the APA requires CMS to adopt a different substantive legal standard. Instead, the Medicare statute contemplates that "if the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of" a proposed rule, as happened here, under section 1871(a)(4) of the Act, "such provision" may still take effect after "further opportunity for public comment and a publication of the provision again as a final regulation." Here, the August 2020 proposed rule provided that further opportunity, and all interested parties have had a full opportunity to share their views on the proper interpretation of the statute. We have fully considered all comments received before finalizing this action.

We are not setting a precedent in this action that the agency can always engage in retroactive rulemaking when courts find that one of our final rules is not a logical outgrowth of the associated proposed rule. Retroactive rulemaking is authorized only when the Secretary determines that retroactive application: (1) is necessary to comply with statutory requirements; or (2) that a failure to do so would be contrary to the public interest. These circumstances will not always be present. For example, as to necessity to comply with statutory requirements, there will

[9] For more information on the FY 2014 IPPS final rule, which became effective October 1, 2013, we refer readers to 78 FR 50614.

not always be, as there is here, a statutory directive to calculate payments that demands an interpretation of the very statutory provision interpreted in the vacated rule coupled with the absence of a prior rule addressing the issue that needs to be resolved (here, how to treat days attributable to Part C enrollees in the DPP).

We do not agree that this retroactive rulemaking has deprived the public of a chance to be heard as the agency has provided a period for comment and considered all the comments submitted.

We also do not agree with the underlying premise that either the APA or the Medicare statute require some sort of punitive "consequences" to an agency as the result of a logical outgrowth deficiency, especially where, as here, the alternative interpretation (that Part C enrollees are not entitled to benefits under Part A) would be contrary to statute. CMS has given the public a chance to submit comments and has considered those comments, thereby curing the procedural error.

*Comment*: Some commenters stated that the DSH statute does not require any specific treatment of Part C days and so retroactive rulemaking is not authorized because retroactivity is not "necessary to comply with statutory requirements" as contemplated by section 1871(e)(i) of the Act. Similarly, a commenter asserted that because the D.C. Circuit in *Northeast* and the D.C. District Court in *Alegent Health-Immanuel Medical Center v. Sebelius*, 917 F. Supp. 2d 1 (D.D.C. 2012), have read the statute to permit excluding Part C days from the Medicare fraction, retroactive rulemaking would not be necessary to comply with the statute. Some commenters stated that retroactive rulemaking is only permitted to adopt what they believe to be CMS' pre-2004 policy.

*Response*: The commenters misunderstand the Secretary's position in the August 2020 proposed rule. Section 1871(e) of the Act authorizes retroactive rulemaking when the Secretary determines that, in order to comply with statutory requirements, it is necessary to apply a "substantive change in regulations, manual instructions, interpretative rules, statements of policy,

or guidelines of general applicability . . . retroactively to items and services furnished before the effective date of the change." Here the DSH statute requires the Secretary to calculate DSH payments by, in part, treating Part C enrollees as either "entitled to benefits under part A" or as not so entitled, but there is no promulgated rule governing the treatment of Part C days for fiscal years before 2014. Therefore, unless the statute itself establishes the substantive legal standard, retroactive rulemaking is required in order make the statutorily required DSH adjustments. In other words, the Secretary's determination that retroactive rulemaking is necessary to comply with statutory requirements is not based on the view that the statute admits of only one interpretation of "entitled to benefits under part A," which the Court in *Empire* has now confirmed. Rather, the basis of the determination is that the statute requires the Secretary to make DSH adjustments, which in turn requires him (to the extent the statute itself contains any ambiguity or "gap") to interpret the phrase "entitled to benefits under part A" as that phrase relates to Part C days, and the Supreme Court has instructed that such an interpretation must be promulgated by notice-and-comment rulemaking. This same conclusion – that retroactive rulemaking is required – results even if CMS found the commenters' preferred treatment of Part C days to be the better interpretation and wished to adopt it. *Northeast* and *Alegent* did not address section 1871 of the Act and have been superseded in some respects by the Supreme Court's decision in *Allina II*.

*Comment*: A commenter stated that CMS has authority to adopt a retroactive rule only if the substantive change in the regulation itself is required, in other words, only if the statute unambiguously requires the proposed interpretation. Some commenters stated that, contrary to the August 2020 proposed rule (as they interpret it), the *Allina* cases created no legal ambiguity and so retroactive rulemaking is not required. Another commenter stated that any legal ambiguity is already resolved by following the precedent of *Northeast*.

*Response*: By its terms, section 1871(e)(1)(A)(i) of the Act permits retroactive rulemaking when the Secretary determines rulemaking is "necessary to comply with statutory

requirements," not only when the Secretary determines that the interpretation embodied in a proposed regulation is itself unambiguously required by the statute. Where the statute admits of only one interpretation, rulemaking (prospective or retroactive) may not be required at all. In *Allina II*, the Court held that rulemaking is necessary under section 1871(a)(2) of the Act when HHS's policy fills a statutory gap. Here, as noted before, the D.C. Circuit previously found that the statute is ambiguous as to whether Part C days are days of beneficiaries "entitled to benefits under Part A," and that the Secretary's interpretation is not foreclosed. Subsequently, in *Empire*, the Supreme Court held that "entitled to benefits under part A" clearly refers to "all those qualifying for the [Medicare] program." (142 S. Ct. at 2368.) We believe this reasoning supports the Secretary's interpretation that "entitled to benefits under part A" includes Part C enrollees since, in order to enroll in Part C, an individual must be entitled to Part A.[10]

Some commenters appear to have misunderstood the discussion of legal ambiguity in the August 2020 proposed rule. In that rule, we stated that failing to finalize a regulation through notice-and-comment rulemaking would create "legal ambiguity" in the future as to the Secretary's treatment of Part C days for fiscal periods before 2014. As noted previously and in the August 2020 proposed rule, until this action is finalized and in effect, no regulation governs the treatment of Part C days for years before FY 2014. Because there is no rule governing the treatment of Part C days for discharges before October 1, 2013, the Secretary concluded he must promulgate a rule that governs this period – whether the rule counts the Part C days in the numerator of the Medicaid fraction (for individuals also eligible for Medicaid), as most commenters desire, or in the Medicare fraction, as CMS proposed. The *Northeast* decision striking down the exclusion of Part C days from the numerator of the Medicaid fraction for FYs 1999 to 2002 and holding that the Secretary could not apply her 2004 interpretation retroactively

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[10] 142 S. Ct. at 2359 ("[E]ntitlement to Part A generally enables a patient to enroll (if he wishes) in Medicare's other programs . . . [including] Part C's coverage.") (citing section 1851(a)(3) of the Act)).

to those years does not control in the face of the Supreme Court's decision in *Allina II*, as discussed throughout this action.

*Comment*: Some commenters stated that there was no missed statutory deadline to justify a retroactive rule.

*Response*: Section 1871(e) of the Act authorizes retroactive rulemaking when the Secretary determines that, in order to comply with statutory requirements, it is necessary to apply a "substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability" or it is in the public interest. The Secretary's authority to undertake retroactive rulemaking is not limited to instances when a statutory deadline has been missed. As explained in this action, the Secretary has determined that retroactive rulemaking is necessary to comply with statutory requirements, to the extent a statutory gap is left to fill after *Empire*, and is in the public interest.

*Comment*: Some commenters stated that the Secretary's argument that retroactive rulemaking is in the public interest is circular because it presupposes that the DSH statute cannot be given effect except through regulation. Some stated that the Secretary's arguments that a retroactive rule would be in the public interest simply repeat his arguments for why a retroactive rule is required by statute.

*Response*: We do not agree that the conclusion that the treatment of Part C days cannot be resolved without rulemaking is a mere presupposition, and therefore that the Secretary's argument is circular. Rather, as stated previously, there is no "promulgated rule governing the treatment of Part C days for fiscal years before 2014" (*Allina Health Servs.*, 863 F.3d at 939), and the Supreme Court held that the Secretary cannot establish or change an avowedly gap-filling policy for the treatment of Part C days without first promulgating a regulation. Thus, to the extent the Supreme Court in *Empire* did not foreclose any other interpretation of the statute than the one the Secretary proposes, the need for rulemaking on the treatment of Part C days under the statute is not a presumption. We also believe it is in the public interest for the

Secretary to enact rulemaking that reflects what he believes is the best interpretation of the statute, one consistent with what the Supreme Court has since described as the clear meaning of the statute, because to do otherwise may result in payments from the Medicare Trust Fund in excess of what he believes is authorized in the DSH statute.

*Comment*: Some commenters stated that the Medicare statute's authorization of a retroactive substantive change in regulations may apply only when the Secretary determines that the change has a positive impact on providers. Similarly, some commenters stated that CMS does not have authority to act retroactively because its proposed rule would cause a loss to most hospitals and the public interest exception was intended to apply only where beneficial to providers. Some commenters relied on language in a 2001 Ways and Means Committee report that stated that a retroactive substantive change would be permissible if it would "have a positive effect on beneficiaries or providers of services and suppliers."

*Response*: By its terms, the statute as enacted does not restrict the Secretary's determination that a retroactive substantive change in regulations is in the public interest only in those instances where the change would have a positive impact on providers. The statute refers to "public interest" not "providers' interest." It is in each providers' interest to receive as much in DSH payments as possible. It is in the public interest that hospitals are paid in accordance with the statute. To the extent that any statutory gap remains following the Supreme Court's *Empire* decision, the Secretary believes rulemaking on the Part C days issue for years prior to the FY 2014 IPPS final rule is required by *Allina II* and is in the public interest. We believe that the interpretation articulated in the August 2020 proposed rule best reflects the statutory text as well as congressional intent. We also believe that applying that interpretation retroactively is in the public interest because the alternative interpretation (that Part C enrollees are not entitled to benefits under Part A) would in many instances result in payments in excess of what Congress intended.

*Comment*: A commenter reasoned that because the D.C. Circuit held in *Allina Health Services v. Price* that CMS could not bypass notice-and-comment rulemaking and resolve the treatment of Part C days through adjudication, which is inherently retroactive, retroactive rulemaking is likewise impermissible.

*Response*: The Medicare statute at section 1871(e)(1)(A) of the Act expressly provides authority for retroactive rulemaking under certain conditions, as explained previously, and for the reasons articulated in the August 2020 proposed rule and in this final action, the Secretary finds that those conditions are met here.

*Comment*: Most commenters opposed CMS's proposal and urged CMS to exclude Part C days from the Medicare fraction of the DPP calculation and include them (for dually eligible individuals) in the numerator of the Medicaid fraction. (We note that, as explained previously, all patient days, regardless of eligibility for Medicaid or entitlement to Medicare Part A, are included in the denominator of the Medicaid fraction.) Many commenters disagreed that individuals enrolled in Part C are "entitled" to benefits under Part A and asserted that the proposed interpretation is inconsistent with their view of the intent of the statute. Commenters cited the following statutory provisions in support of their arguments:

- Section 226(c)(1) of the Act, which states that entitlement of an individual to hospital insurance benefits for a month under Part A "shall consist of entitlement to have payment made under, and subject to the limitations in, part A."

- Section 1851(a)(1) of the Act, which states persons eligible for Medicare Advantage are "entitled to elect to receive benefits" either "through the original Medicare fee-for-service program under parts A and B" or "through enrollment in a [Medicare Advantage plan] under [Part C]."

- Section 1851(i)(1) of the Act, which states that "payments under a contract with a [Medicare Advantage] organization . . . with respect to an individual electing a [Medicare

Advantage] plan . . . shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A and B…"

Commenters contended that individuals who enroll in an MA plan receive benefits under Part C and not Part A, and so cannot be "entitled" to benefits under Part A. Some stated that, because the payments received by providers under contract with the MA organization are made instead of the amounts that would otherwise be payable under Part A, Part C enrollees are not entitled to benefits under Part A. Some commenters stated that a patient who is enrolled in Part C on a given patient day is not entitled to Part A benefits "for that hospitalization"; several argued that while a beneficiary must at some point be entitled to benefits under Part A in order to enroll in Part C, once they do so they are no longer entitled to benefits under Part A. Similarly, a commenter suggested that the benefits to which beneficiaries are entitled under Part A are "subject to the limitations" of Part A, but Part C enrollees may receive benefits from their MA plans that are in excess of benefits to which they are entitled under Part A, such that beneficiaries must not be entitled to benefits under Part A.

*Response*: We disagree with the commenters, and we believe the Supreme Court's intervening decision in *Empire* now forecloses the commenters' interpretation. (142 S. Ct. 2354, 2368.) Indeed, even before *Empire*, we did not find these comments persuasive. These comments are the same or similar to comments CMS received in response to the proposed prospective rule concerning the treatment of Part C days that was finalized in the FY 2014 IPPS final rule.[11] We continue to disagree that Medicare beneficiaries enrolled in Part C no longer receive benefits under Part A and that, because the payment structure of Part C applies (that is, CMS pays the MA plans so that the plans may make payments to hospitals for the care of the beneficiaries), those beneficiaries are not entitled to Part A benefits. As we stated in the FY 2014 final rule, section 226 of the Act provides that an individual is automatically "entitled" to

[11] For more information on that rule, including a summary of the comments received, we refer readers to 78 FR 50496.

Medicare Part A when the person reaches age 65, provided that the individual is entitled to Social Security Benefits under section 202 of the Act, or becomes disabled.

We continue to believe, as we concluded in the FY 2014 IPPS final rule, that Congress uses the phrase "entitled to benefits under part A" consistently to refer to an individual's legal status as a Medicare Part A beneficiary. This phrase is used in numerous other sections of the Medicare statute, indicating that it has a specific, consistent meaning throughout the statutory scheme, rather than a varying, context-specific meaning in each section and subsection. Enrolling in Part C does not change an enrollee's status as a Medicare Part A beneficiary and does not remove or reduce any benefits the beneficiary would otherwise have received; indeed, the MA plan must provide the benefits to which the beneficiary is entitled under Part A as described by section 1852(a)(1)(A) and (B)(i) of the Act and may provide additional supplemental benefits as described by section 1852(a)(3)(C) of the Act. The D.C. Circuit rejected many of the commenters' views that the agency's interpretation is inconsistent with the plain language of the statute. (*Northeast*, 657 F.3d at 6-13.) We note that the Supreme Court in *Empire* further explained that, for purposes of calculating hospitals' DPPs, "individuals 'entitled to [Medicare Part A] benefits' are *all those qualifying for the program*" and that entitlement to Part A benefits is, "according to the statute, simply a legal status arising from" meeting the statutory criteria in section 226(a)-(b) of the Act. (142 S. Ct. 2354 at 2368 and 2363 (emphasis added).) A person's entitlement to Part A benefits arises when the "person meets the basic statutory qualifications and (unless a disability diminishes) never goes away." (*Id.* at 2364.)

In response to commenters' concerns about section 226(c)(1) of the Act, we note that, for purposes of section 226(c)(1) of the Act, beneficiaries enrolled in Part C are having payment made under Part A for the month in question, via the Part A component of the monthly payment made to the MA organization, and are receiving Part A benefits subject to the limitations on such benefits provided for in Part A.

In response to commenters' concerns about section 1851(a)(1) of the Act, we note that, for purposes of section 1851(a)(1) of the Act, the "benefits" referenced in the phrase quoted by the commenters ("entitled to elect to receive benefits") are the benefits provided for in Part A and Part B. Thus, this language confirms that beneficiaries enrolled in Part C remain "entitled" to benefits under Part A, and thus supports our interpretation of the statute. It is only the vehicle "through" which such Part A benefits are received that changes, from the "fee-for-service" method spelled out under Part A to the capitation payment method spelled out in Part C.

Section 1851(i)(1) of the Act similarly refers only to whether Part A benefits are provided via payments to, and by, the MA organization or direct payments made under the "fee-for-service" payment procedures provided for in Part A and Part B. It is only the process for furnishing these benefits that is at issue in the provision, not entitlement to such benefits themselves. That Part C enrollees may receive supplementary benefits beyond what other Part A-entitled beneficiaries are entitled to does not deprive the Part C enrollees of entitlement to Part A benefits.

Commenters who argue that it is obvious that a beneficiary cannot be entitled to both Part C and Part A benefits on the same day confuse the method for covering Part A benefits with whether an individual is entitled to receive such benefits. The question of whether a beneficiary is "entitled" to Part A benefits is distinct from how the provider is paid for furnishing those benefits. As we stated in the August 2020 proposed rule (85 FR 47725), and has been subsequently affirmed by the Supreme Court in *Empire*, section 226 of the Act identifies statutory criteria for an individual's entitlement to Part A benefits. (142 S. Ct. at 2362.) Beneficiaries who are enrolled in MA plans provided under Medicare Part C continue to meet all the statutory criteria for entitlement to Medicare Part A benefits under section 226 of the Act. Moreover, section 1851(a)(3) of the Act provides that, in order to be eligible to enroll in Medicare Part C, a beneficiary must be "entitled to benefits under Part A and enrolled under Part B." Thus, by definition, a beneficiary must be entitled to Part A to be enrolled in Part C.

We do not believe that the Act suggests that beneficiaries who enroll in a Medicare Part C plan thereby forfeit their entitlement to Medicare Part A benefits. To the contrary, as affirmed in *Empire*, because they continue to meet the basic statutory criteria for entitlement under the statute (that is, being over 65 or disabled), their entitlement status is unaffected by such enrollment. (142 U.S. at 2362.) In our view, enrollment in a plan under Medicare Part C is simply an option that a person entitled to Part A benefits may choose as a way to receive their Part A benefits. A beneficiary who enrolls in Medicare Part C is entitled to receive benefits under Part A through the MA plan in which he or she is enrolled, and the MA organization's costs for providing such Part A benefits are paid for by CMS with money from the Medicare Part A Trust Fund.

In addition, under certain circumstances, Medicare Part A pays providers directly for care furnished to patients enrolled in Medicare Part C plans, rather than indirectly through capitated payments to MA organizations from the Medicare Part A Trust Fund. For example, under section 1852(a)(5) of the Act, if, during the course of the year, the scope of benefits provided under Medicare Part A expands beyond a certain cost threshold due to Congressional action or a national coverage determination, Medicare Part A will pay providers directly for the cost of those services provided to beneficiaries enrolled in Part C. Similarly, Medicare Part A pays directly for hospice care (a Part A benefit) furnished to MA patients who elect under section 1812(d) of the Act to receive such care from a particular hospice program and, under certain circumstances, for FQHC services provided to MA patients for FQHCs that contract with MA organizations under sections 1853(h)(2) and 1853(a)(4) of the Act, respectively. Thus, we continue to believe that a patient enrolled in an MA plan remains entitled to benefits under Part A and should be counted in the Medicare fraction, not in the numerator of the Medicaid fraction (should the Part C enrollee also be eligible for Medicaid). Indeed, in light of the Supreme Court decision in *Empire*, we do not believe the statute can properly be read otherwise.

*Comment*: Some commenters stated that the Secretary's interpretation of "entitled to benefits under part A" in the DSH statute is inconsistent with his interpretation of "entitled to [SSI] benefits" in that same statute because he treats people as "entitled" to Medicare Part A benefits if they meet the statutory criteria for entitlement, regardless of whether Medicare pays for hospital services during a given hospital stay, but treats patients as "entitled" to SSI benefits only if they are actually paid those monthly cash benefits for the month(s) in which they are hospitalized. Some commenters suggested that, if CMS interprets "entitled" to Medicare to include unpaid days it must include in the Medicare fraction numerator days for beneficiaries who are (they argue) "entitled" to SSI but who do not receive any cash benefit. Some commenters proposed additional Social Security Administration status codes that, in their opinion, should be included in the numerator of the Medicare fraction because they capture individuals who, purportedly, are entitled to SSI.

*Response*: The meaning of "entitled to [SSI] benefits" in the DSH statute is beyond the scope of this action. However, we note that, as the Secretary explained in the FY 2014 IPPS final rule (78 FR 50617), the differing interpretation of these two distinct phrases is based on the two different kinds of entitlements at issue. Because SSI is a cash benefit, and because entitlement to that benefit depends on factors (such as income level) that can change over time, only a person who is actually entitled to be paid these benefits for the month in question is considered entitled to those benefits. This differs from entitlement to Medicare benefits under Part A, which are a distinct set of health insurance benefits where an individual's entitlement to such benefits does not generally evolve over time. The health insurance benefits also include ongoing, continuous coverage for various specified kinds of healthcare service, regardless of income status or other financial factors.[12] The Secretary has more extensively addressed these two different kinds of entitlement for purposes of the DSH calculation in another notice-and-

[12] 142 S. Ct. at 2363 (emphasizing that Part A entitlement under the statute "reflects the complexity of health insurance").

comment rulemaking. For more information, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50275 through 50286). That rulemaking further elaborates on the reasons for distinguishing between entitlement to SSI benefits and entitlement to Medicare benefits under Part A. (*Id.* at 75 FR 50280 and 50281.) We note also that courts have upheld the Secretary's distinction between these two different kinds of entitlement against similar allegations of "inconsistency."[13]

*Comment*: Some commenters stated that the August 2020 proposed rule did not discuss the phrase "for such days" in the DSH statute and impermissibly seeks to eliminate that statutory clause through rulemaking. Other commenters state the phrase "for such days" could or must be interpreted to exclude Part C days from the Medicare fraction, which includes days for patients who "(for such days) were entitled to benefits under part A." (Section 1886(d)(5)(F)(vi) of the Act.) These commenters believe this phrase requires that, to be included in the Medicare fraction, a patient must be entitled to Part A hospital benefits on the patient day being counted, and that Part C-enrolled patients are not so entitled.

Some commenters agree with then-Judge Kavanaugh's concurrence in *Northeast* when he reasoned that the statute's use of "were" indicates that the calculation of the Medicare fraction is meant to determine "what kind of benefits a specific patient received on a specific day" and so HHS must "isolate hospital days attributable to patients who were, on those days, receiving benefit payments through Part A of Medicare," which in his (and the commenters') view excludes a Part C enrollee. (*Northeast*, 657 F.3d. at 19 (Kavanaugh, J., concurring).) Moreover, these commenters assert that since a patient who is receiving benefits under Part A for a given day cannot also receive benefits under MA for that day, the "for such days" language indicates there is a clear delineation between MA days and Medicare Part A days.

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[13] *Metro. Hosp. v. HHS*, 712 F.3d 248, 268 (6th Cir. 2013); *Advoc. Christ Med. Ctr. v. Azar*, No. 17-CV-1519 (TSC), 2022 WL 2064830, at *9 (D.D.C. June 8, 2022); *Florida Health Scis. Ctr. v. Becerra*, 19-cv-3487-RC, 2021 WL 2823104, at *15-16 (D.D.C. July 7, 2021).

*Response*: The Secretary's interpretation does not seek to eliminate the clause "for such days." As the Supreme Court explained in *Empire*:

> The "(for such days)" phrase instead works as HHS says: hand in hand with the ordinary statutory meaning of "entitled to [Part A] benefits." The parenthetical no doubt tells HHS to ask about a patient on a given day. But the query the agency must make is not whether that patient on that day has received Part A *payments*; the query is, consistent with what "entitled" means all over the statute, whether that patient on that day is *qualified* to do so.

142 S. Ct at 2365 (emphasis added). We note that Justice Kavanaugh authored the dissenting opinion in *Empire,* adhering to his view in his *Northeast* concurrence. The majority in *Empire* accepted the Secretary's view and necessarily rejected then-Judge Kavanaugh's interpretation of "for such days" in *Northeast*.

In the Secretary's view, Part C enrollees are entitled to all Part A benefits (including hospital benefits) regardless of how those benefits are (or are not) paid, that is they are "entitled" to Part A benefits when providers are paid by an MA organization (which in turn is paid from the Part A trust fund) and also when providers are paid directly from the Part A trust fund, such as in the case of hospice benefits. Part A entitlement is a status that does not change with enrollment in Part C. The Secretary's interpretation, which is the same one adopted by the Supreme Court in *Empire*, gives meaning to the clause "for such days" and does isolate hospital days attributable to patients who were entitled to – meaning qualified for – Part A benefits on specific patient days. An individual's entitlement to Medicare Part A is largely, but not perfectly static, and "[n]ot every patient who meets the criteria . . . during some portion of his hospital stay will meet those criteria for all of the stay." *Northeast*, 657 F.3d at 12. For example, "a person who collects Social Security and who turns 65 during his hospital stay will become 'entitled' to benefits under Part A on his sixty-fifth birthday," and "a person under age 65 who reaches his twenty-fifth calendar month of entitlement to disability benefits under [section 223 of the Act] during his hospital stay will become 'entitled' to benefits under Part A upon reaching his twenty-fifth month of disability

entitlement." (*Id.*) For such beneficiaries, the days before they become entitled to benefits under Part A are excluded from the Medicare fraction, but the days on or after they become entitled to benefits under Part A are included in that fraction.[14]

Although our interpretation of the statute is not driven by the financial impact of that interpretation, we note also that excluding Part C days from the Medicare fraction based on the commenters' understanding of the statutory phrase "for such days" may put some hospitals in a *worse* position than the Secretary's view because those days would not necessarily be includable (for individuals also eligible for Medicaid) in the Medicaid fraction. The statutory language defining the Medicaid fraction only counts in that fraction patient days attributable to patients who "were not entitled to benefits under part A [of Medicare]" (section 1886(d)(5)(F)(vi)(II) of the Act); that phrase is not modified with the same "for such days" phrase that is present in the statutory language defining the Medicare fraction (section 1886(d)(5)(F)(vi)(I) of the Act). Therefore, under *Empire*, "the 'not entitled' phrase in [the Medicaid fraction] should mean (consistent with the rest of the statute) not qualifying for Medicare," which includes Part C enrollees that the commenters "would oust from the Medicare fraction," and those Part C enrollees thus would "fall . . . outside the Medicaid fraction," too. (142 S. Ct. at 2367.)

*Comment*: A commenter stated that because the statute expressly references Part C days in the indirect medical education (IME) provisions of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) in order to provide IME payments to hospitals in connection with patients enrolled in Part C plans, but did not also change the DSH statute to expressly refer to Part C days, the DSH Medicare fraction should not be interpreted to include Part C days and the Medicaid fraction should not be interpreted to exclude Part C days because Congress did not mean for Part A and Part C to be synonymous.

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[14] *Empire*, 142 S. Ct. at 2366 ("By the way, said Congress . . . : If someone turns 65 during the year the fraction covers, make sure to exclude his pre-birthday hospital days.").

*Response*: The IME add-on for patients enrolled in Part C plans under section 1886(d)(5)(B) of the Act is designed to compensate IPPS teaching hospitals for increases in costs that are presumed to occur as an indirect consequence of the involvement of student doctors in patient care. Payments for IME costs in traditional Medicare are calculated on the basis of payments for discharges (Section 1886(d)(5)(B) of the Act); this language does not include any reference to entitlement to Part A benefits. Prior to the BBA, Medicare did not make any separate payment to hospitals for IME costs associated with Medicare patients enrolled in Part C plans. Sections 4622 and 4624 of the BBA directed the Secretary to provide for an additional payment amount to hospitals for IME in connection with Medicare beneficiaries enrolled in a Part C plan. Congress expressly referenced Part C in the IME provisions of the BBA because neither hospitals nor Part C plans are paid by the Secretary on the basis of discharges of Part C enrollees. (Section 1886(d)(5)(B) of the Act.) We disagree with the commenter that because the DSH statute does not expressly mention Part C days, the statute unambiguously treats such days as days for which beneficiaries are not entitled to Part A. Rather, other statutory provisions contemplate that Part C enrollees remain entitled to Part A, indicating that the statute includes them in the Medicare fraction. The Secretary's position is not that "Part A" and "Part C" are synonymous, but that Part C enrollees remain entitled to benefits under Part A.

*Comment*: A commenter stated that CMS is proposing to remove the word "covered" from the regulation. Other commenters stated that CMS implicitly conceded that Part C days are not "covered" days when it stated in the FY 2014 IPPS final rule that the corresponding proposed rule did not propose any change to the text of the regulation because "the current text [already] reflects the policy [that was] proposed" (78 FR 50615). The commenters appeared to mean that if, in CMS's view, the text of the regulation did not need to change in the FY 2014 IPPS final rule in order to include Part C days in the Medicare fraction, that is because the word "covered" had already been removed from the text of the regulation.

*Response*: We disagree with the suggestion that in the August 2020 proposed rule, CMS proposed to remove the word "covered" from the regulation; the regulation had already been revised to remove the word "covered" (69 FR 49099). Although the FY 2005 IPPS final rule was vacated by the D.C. Circuit as to its treatment of Part C days in *Allina I*, that decision did not address the issue of exhausted benefit days; that is, days that are not "covered." Before we proposed the August 2020 proposed rule, the regulation had already been revised to remove the word "covered" (69 FR 49099). We also disagree with the commenters' interpretation that the statement in the FY 2014 IPPS final rule implied that Part C days are not "covered days." When CMS stated in the FY 2014 IPPS proposed rule that the text already reflected the proposed policy, that was because the text of 42 CFR 412.106(b)(2)(i)(B) and (b)(2)(iii)(B) expressly included Part C days in the Medicare fraction numerator and denominator, not because the word "covered" had already been removed from the regulation. In the FY 2005 IPPS final rule, the agency had stated that it was "revising [its] regulations" – which at the time simply parroted the language of the statute – to specifically "include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation" (69 FR 49099). Although, the agency inadvertently failed to make that revision in the text of the regulations at that time, the Secretary made a "technical correction" to the regulations in 2007 to expressly incorporate the interpretation announced in the FY 2005 IPPS final rule. (72 FR 47384 (August 22, 2007))

*Comment*: A commenter read our description of the alternative considered in the August 2020 proposed rule to contemplate the restoration of the term "covered" to the DSH regulation (meaning that exhausted benefit or unpaid days would not be included in the calculation of the Medicare fraction), which the commenter favored.

*Response*: This commenter misunderstood our proposal and the alternative considered. As discussed in more detail elsewhere in the action, under both our proposal and the alternative considered, Part C days would be treated as "covered" days for the purposes of calculating a hospital's DPP and neither the rule proposed nor the alternative considered directly addressed the

status of exhausted benefit or other unpaid days. As we did not propose the change the commenter supports, we will not be adopting the commenter's suggestion.

*Comment*: A commenter stated that the August 2020 proposed rule is arbitrary and capricious because the Secretary excludes from the Medicare fraction patient days paid under Medicare Part B and patient days for areas of a hospital not payable under Part A.

*Response*: The August 2020 proposed rule is not inconsistent with the exclusion of Part B days from the Medicare fraction; to enroll in Part B under section 1836 of the Act, an individual need not be "entitled to benefits under part A." In a December 2, 2015 decision on remand in *Allina I*, the Administrator explained that the restriction on patient days to certain units of the hospital is entirely unrelated to the Secretary's interpretation of "entitled to benefits under part A" but is instead based on an interpretation of the term "patient days" in the DSH provision as limited to inpatient days payable under the IPPS.

*Comment*: Several commenters stated that the August 2020 proposed rule is inconsistent with the D.C. Circuit's holding in *Allina Health Services v. Price*, 863 F.3d 937 (D.C. Cir. 2017) and the Supreme Court's decision in *Allina II* because those cases held that the Secretary cannot undertake a policy change without first promulgating a regulation. Several commenters stated that the August 2020 proposed rule disregarded or circumvented the Supreme Court's holding in *Allina II*. Some commenters stated that CMS must not interpret the statute to treat Part C days as days beneficiaries are entitled to benefits under Part A because CMS has, purportedly, gotten more than one adverse decision on this issue. They argue that the higher DSH payments that would be calculated by excluding these days from the Medicare fraction and including them in the Medicaid fraction numerator (for patients also eligible for Medicaid) have therefore been wrongfully withheld from providers for many years.

*Response*: We agree that the Supreme Court in *Allina II* held that, because the policy on the treatment of Part C days in the DSH calculation was intended to address an avowed statutory gap, the Secretary cannot establish or change such a policy without first promulgating a

regulation. The purpose of this final action is to comply with that requirement (to the extent any gap-filling policy is even necessary now that the Supreme Court has clarified the meaning of "entitled to benefits under part A," as discussed more elsewhere), not to disregard or circumvent the Court's ruling. As stated in *Allina Health Services*, there is "no promulgated rule governing the [treatment of Part C days] for the fiscal years before 2014." (863 F.3d at 939.) The Secretary explained in briefing to the Supreme Court in *Allina II* that if the Medicare statute required the Secretary's interpretation of "entitled to benefits under part A" to be promulgated through notice-and-comment procedures (as the Supreme Court ultimately held), then notice-and-comment rulemaking would also be necessary before the Secretary could adopt the respondents' preferred interpretation. And, even if considered retroactive in application, this action will not be effective until after the completion of this notice-and-comment rulemaking, which will have given interested parties the opportunity to present their arguments as to the proper interpretation of the statute and given the Secretary the opportunity to consider those arguments before the action is finalized.

No final binding court decision has found fault with the Secretary's interpretation of "entitled to benefits under part A" to include Part C enrollees. That is why, after the Supreme Court issued its *Allina II* decision, the United States District Court for the District of Columbia remanded to the Secretary cases presenting the Part C days issue, holding that the district court had "no basis to direct the agency as to what the formula for the [DSH] recalculation should be" because "this was the aspect of the case left open by previous opinions." (*In Re Allina II-Type DSH Adjustment Cases*, Misc. No. 19-0190, Dkt. 74 (D.D.C. Jan. 19, 2021).)

Indeed, the weight of authority—in our view—now conclusively shows that the Secretary's interpretation of the relevant phrase is permissible, if not required, under the language of the statute. In *Northeast*, the D.C. Circuit held that "the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat 251, which enacted M+C, as well as subsequent amendments to Part C, assume that a person enrolled in [Part C] remains entitled to benefits under Part A, and

nothing in the text or structure of the DSH fractions compels a different result." Most importantly, the Supreme Court's decision in *Empire* has now confirmed the validity of the Secretary's interpretation. While *Empire* addressed exhausted benefit and other unpaid days, not Part C days, the Court's reasoning confirms that "entitled to benefits under part A" should be read to include Part C days. The Court concluded that the statutory text is clear: "being 'entitled' to Medicare benefits . . . means—in the [DSH] fraction descriptions, as throughout the statute—meeting the basic statutory criteria." (*Empire*, 142 S. Ct at 2362.) Part C enrollees, who by definition must be "entitled" to Part A benefits, necessarily meet these basic statutory criteria. They do not cease to meet them through enrollment in Part C because such enrollment does not affect their age or disabled status.

*Comment*: Some commenters stated that CMS did not change what they call its "covered days" rule when Part C was added to the statute, and that CMS has acknowledged that, before the FY 2005 IPPS final rule, it had a practice of excluding Part C days from the Medicare fraction. The commenters appear to suggest that the pre-FY 2005 regulation therefore excluded Part C days from the Medicare fraction because they are (purportedly) not "covered days."

*Response*: This argument was made by plaintiffs in *Allina Health Services v. Price*, 863 F.3d 937, 939 (D.C. Cir. 2017) and rejected by the D.C. Circuit, which held in that case that "HHS *has no promulgated rule* governing the interpretation of 'entitled to benefits under part A' for the fiscal years before 2014." (Emphasis added.) The 1986 regulation, which preceded the FY 2005 IPPS final rule, established the limitation to "covered" days and was promulgated more than a decade before the creation of Medicare Part C and thus plainly could not have addressed whether enrollees in the later-created Part C program are "entitled to benefits" under Part A. And the "covered" days limitation in the pre-FY 2005 IPPS final rule was not based on any interpretation of "entitled to benefits under part A," nor did it establish any policy that would have excluded Part C days. Rather, as the Secretary explained in the 1986 rulemaking, the rule was intended to clarify that it "refer[red] only to Medicare covered days," that is, days for which

Medicare is authorized to make payment.[15] The "covered" limitation was an interpretation of the statutory phrase "for such days," which modifies the phrase "entitled to benefits under part A" (51 FR 31460 and 31461). The determination of whether a patient day is "covered" has never depended on whether the day is attributable to an individual under the traditional Part A fee-for-service program or one enrolled in a managed care plan, such as under Part C. A Part C enrollee is entitled to receive benefits under Part A through the Part C plan in which he is enrolled, and such benefits are paid from the Medicare Part A Trust Fund. (Section 1853(f) of the Act.) Therefore, Part C days have always been considered to be paid or "covered" days even though Medicare payments for Part C days are made to managed care plans rather than directly to hospitals.

*Comment*: Some commenters stated that because the Ninth Circuit in *Empire v. Becerra*, 958 F.3d 873 (2020), vacated CMS's regulatory amendment in the FY 2005 IPPS final rule that removed the word "covered" from the DSH regulation, and (purportedly) did so on a nationwide basis, the previous regulation was reinstated and so only "covered" days can be included in the Medicare fraction. According to these commenters, Part C days can therefore not be included in the Medicare fraction because they are not paid for under Part A and so are not "covered" days. These commenters also believe that the Secretary ought to have discussed *Empire* in the proposed rule.

*Response*: The Supreme Court reversed the Ninth Circuit's decision in *Empire*, concluding that "individuals 'entitled to [Medicare Part A] benefits' are all those qualifying for the program, regardless of whether they are receiving Medicare payments for part or all of a hospital stay." (142 S. Ct. at 2368 (alteration in original).) *Empire* did not involve the treatment of Part C days, nor did the Ninth Circuit's analysis of its own prior precedent bear directly on that issue, which is why the Ninth Circuit's holding was not discussed in the August 2020

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[15] See the September 3, 1986 **Federal Register** (51 FR 31460 and 31461) and 42 CFR 409.3 ("Covered" refers to "services for which the law and the regulations authorize Medicare payment.").

proposed rule. Regardless, and putting aside the fact that the Ninth Circuit's decision in *Empire* was overturned by the Supreme Court, any relevance of the Ninth Circuit's decision in *Empire* to the Part C days issue would lie only in the Ninth Circuit's interpretation of "entitled to benefits under part A," an issue that was addressed at length in the August 2020 proposed rule. The Secretary has explained why Part C enrollees remain entitled to benefits under Part A and also that, because MA plans are paid from the Part A trust fund and use such payments to pay hospitals for Part C days, Part C days are "covered" days. Accordingly, the Ninth Circuit's conclusion that only "covered" or paid days are included in the Medicare fraction would not have required the exclusion of Part C days. In any event, the Supreme Court's holding in *Empire* that individuals who meet the basic statutory criteria for Medicare Part A benefits are "entitled to benefits under part A," and their patient days are included in the Medicare fraction, has now confirmed the Secretary's interpretation.

*Comment*: Some commenters stated that CMS must apply what they assert is its pre-FY 2005 practice of excluding Part C days from the Medicare fraction. Of these, some rely on *CropLife America v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003), and *Action on Smoking & Health v. C.A.B.*, 713 F.2d 795, 797 (D.C. Cir. 1983), for the proposition that when an agency's rule is vacated, the agency's previous practice is reinstated. In *Action on Smoking* the Court of Appeals held that its vacatur of the challenged portion of a rule "had the effect of reinstating the rules previously in force." In *CropLife America* the Court of Appeals held that the consequence of vacatur of a rule was the restoration of "the agency's previous practice." Some of these commenters stated that CMS must therefore exclude Part C days from the Medicare fraction and include them in the Medicaid fraction (for individuals also eligible for Medicaid) either based on the pre-FY 2005 regulation or based on a "clarification" of its regulation to reflect the pre-FY 2005 "policy" for years before the effective date of the prospective rule. Some commenters stated that the Supreme Court's *Allina II* decision does not prevent CMS from reverting to its prior practice because the statute requires notice and comment only for "rule[s], requirement[s]

or other statement[s] of policy," not practices. Some commenters stated that the pre-FY 2005 practice could be reinstated without notice-and-comment rulemaking because the practice did not impose any "requirement" to which section 1871(a)(2) of the Act would apply, unlike the FY 2005 IPPS final rule that was vacated in *Allina I*. A commenter relied on *Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914 (D.C. Cir. 2013), in support of their argument that, whether a prior policy or practice is valid is irrelevant to the question of whether retroactive rulemaking is permissible; it matters only that such policy existed.

*Response*: To the extent these comments suggest that the agency must apply an alleged pre-FY 2005 practice of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction, we believe that approach would violate existing law. First, as discussed in more detail previously, we believe that the statute, as construed in *Empire*, does not reasonably permit the agency to treat persons enrolled in Medicare Advantage as not "entitled" to benefits under Part A. Second, to the extent that the statute, as construed in *Empire*, does not itself establish the applicable substantive legal standard, then the Supreme Court's *Allina II* decision requires the agency to engage in notice-and-comment rulemaking to address whatever statutory "gap" might remain as to that issue. We do not agree that the agency could, consistent with *Allina II*, adopt an approach on the treatment of Part C days by relying on an alleged pre-FY 2005 practice, even if the practice could be said to amount to a "policy." If rulemaking was required to change the Secretary's approach, as held in *Allina II*, then rulemaking was also required to establish the Secretary's approach in the first place.

Moreover, in a December 2, 2015 decision on remand in *Allina I*, the Administrator determined that "it has never been CMS policy for Part C days to be included in the numerator of the Medicaid fraction, nor has CMS included such days" as a matter of practice. The Secretary's practice prior to FY 2005 was to exclude Part C days from both the Medicare fraction and from the numerator of the Medicaid fraction (for individuals also eligible for Medicaid), and no approach to Part C days was embodied in a notice-and-comment rule before the now-vacated

rule. We recognize that the D.C. Circuit in *Northeast* stated, in the context of discussing retroactivity, that the agency had a pre-FY 2005 "practice" of excluding Part C days from the Medicare fraction (657 F.3d at 17), but that case did not hold that this practice amounted to a policy or that the agency had adopted a legal interpretation of the statute that would require the Secretary to account for Part C days in the manner preferred by providers. Most importantly, the D.C. Circuit has confirmed that any such practice, however characterized, did not amount to a notice-and-comment rule, as required to establish a gap-filling policy under the Supreme Court's *Allina II* decision. Specifically, the D.C. Circuit found that HHS has "no promulgated rule" governing the treatment of Part C days for fiscal years prior to FY 2014. (863 F.3d at 939.)

Neither *CropLife* nor *Action on Smoking and Health* were Medicare cases and so they did not address section 1871(a)(2) of the Act. Under the Supreme Court's opinion in *Allina II*, pursuant to that provision a "substantive legal standard" concerning the treatment of Part C days can be established or changed only via notice and comment rulemaking, not merely by practice. Contrary to some commenters' suggestion, there is no valid substantive legal standard embodied in agency practice that the agency could "reinstate" for years prior to the effective date of the prospective rule, nor any "policy" created by adjudication or otherwise. The prior practice did not establish any policy consistent with section 1871(a)(2) of the Act as construed by the Supreme Court in *Allina II.* No commenter identified statutory language, or language from the Supreme Court in *Allina II*, that would suggest that the Secretary could establish a substantive legal standard concerning the treatment of Part C days simply by adopting a practice in the absence of notice-and-comment rulemaking.

As noted, the agency's prior practice was generally to exclude the days from both the Medicare fraction and the numerator of the Medicaid fraction (for individuals also eligible for Medicaid). In order to resolve the Part C days issue for pending appeals for cost years ending before the effective date of the prospective FY 2014 IPPS final rule, CMS must put these days in either the Medicare fraction or in the Medicaid fraction numerator (for individuals also eligible

for Medicaid). In other words, CMS must instruct its contractors as to where these days are to be placed for DSH calculations for pending appeals. We do not agree that, after holding that the agency did not follow the proper procedure in adopting a policy regarding the treatment of Part C days after its rule was vacated, the Supreme Court contemplated that the Secretary could simply adopt a policy by reverting to an alleged prior practice that could not itself have established any policy under the terms of section 1871(a)(2) of the Act.

We also do not agree that the Secretary could finalize a rule that "clarifies" or "codifies" the regulation to reflect what some commenters refer to as the pre-FY 2005 "policy." First, we believe that the characterization of the agency's practice of generally excluding Part C days from the Medicare fraction as a "policy" is mistaken. As already noted, and as we explained in the prospective FY 2014 IPPS final rule (78 FR 50496), as a matter of practice, the Secretary generally excluded these days from both the Medicare fraction and the numerator of the Medicaid fraction (for individuals also eligible for Medicaid). In order for a regulation to reflect the general pre-FY 2005 practice, the Secretary would have to interpret the DSH statute to treat Part C days as both days on which beneficiaries are "not entitled to benefits under part A" (and thus to be excluded from the Medicare fraction) AND "entitled to benefits under part A" (and thus to be excluded from the numerator of the Medicaid fraction (for individuals also eligible for Medicaid)). Such an interpretation would not be a "clarification," as it would interpret the phrase "entitled to benefits under part A" in two different ways in the same clause of the statute and would not be in accord with *Allina I*, 746 F.3d at 1108, which stated that the statute "unambiguously" requires Part C days to be counted in one fraction or the other because "a Part C-enrolled individual is either eligible for Medicare Part A, or not." *Id*. Second, as discussed further elsewhere, such a policy would be inconsistent with what the Supreme Court has now held in *Empire* is the clear meaning of "entitled to benefits under part A": "meeting the basic statutory criteria." (142 S. Ct. 2362.) Part C enrollees must meet the basic statutory criteria to enroll in Part C and do not cease to meet them through enrollment in Part C. For these reasons,

we believe it would be legally impermissible to adopt a rule that codifies the agency's past practice.

*Comment*: Some commenters stated that CMS's prior practice (before FY 2005) was to exclude Part C days from the Medicare fraction and include them in the Medicaid fraction. Some commenters stated the D.C. Circuit held in *Allina I* that prior to FY 2005 the Secretary put Part C days in the Medicaid fraction.

*Response*: As explained previously, in a December 2, 2015 decision on remand in *Allina I*, the Administrator determined that "it has never been CMS policy for Part C days to be included in the numerator of the Medicaid fraction, nor has CMS included such days" as a matter of practice. Part C days were thus generally excluded from both fractions, and no regulation governed the issue before FY 2005. And in *Allina I*, the D.C. Circuit did not hold that the Secretary had a policy of putting Part C days in the Medicaid fraction, but instead stated, in connection with the logical outgrowth challenge at issue there, that "a party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, i.e., one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction." (746 F.3d at 1108.) But the Court of Appeals did not say that this *was* CMS's actual policy or practice.

*Comment*: A commenter argued that the proposed interpretation is inconsistent with statements the Secretary made in the **Federal Register** (68 FR 45419) stating that section 1886(d)(5)(F) of the Act requires him to consider only inpatient days to which the prospective payment system applies.

*Response*: The commenter mischaracterizes our statement in the **Federal Register**, which was discussing our interpretation of "patient days" and was unrelated to when a patient is considered entitled to benefits under Part A.

*Comment*: Numerous commenters stated that higher payments to hospitals, especially safety net hospitals, and especially during and in light of the COVID-19 pandemic, are in the

public interest, with some commenters specifying programs they state they cannot expand without higher DSH payments.  Commenters also asserted that many hospitals will receive less in DSH payments under the Secretary's proposed interpretation than they would under the alternative interpretation that Part C enrollees are not "entitled to benefits under part A," and therefore they suggested the public interest lies in making DSH adjustments using their preferred interpretation.  Similarly, some commenters criticized the August 2020 proposed rule for suggesting that, in the Secretary's (purported) view, the alternative model is not in the public interest because it costs more than would effectuating the proposed model.  A commenter stated that the "public interest" exception does not apply merely because the agency is required to pay monies that it owes.

*Response*:  We are adopting the interpretation of "entitled to benefits under part A" that we believe best comports with the statute enacted by Congress.  Indeed, based on the Supreme Court's decision in *Empire*, we believe our interpretation is the only reasonable interpretation. We also do not agree it would be good public policy or in the public interest to promulgate a retroactive rule embodying the interpretation that beneficiaries enrolled in Part C are not entitled to Part A.  Not only would this be a change from the position CMS has articulated consistently for many years, we believe that such an interpretation, in many instances, would result in payments in excess of what Congress authorized in the DSH statute and would be contrary to the Supreme Court's holding in *Empire* that a beneficiary is "entitled to benefits under part A" whenever he meets the statutory criteria for entitlement.

In any event, for all the reasons articulated in the August 2020 proposed rule and reiterated in this final action, we believe the better interpretation by far is that beneficiaries enrolled in Part C remain "entitled to benefits under part A."  And the Supreme Court's decision in *Empire* confirms this view, given its holding that, in the Medicare fraction of a hospital's DSH adjustment, "individuals 'entitled to [Medicare Part A] benefits' are all those qualifying for the program, regardless of whether they are receiving Medicare payments for part or all of a hospital

stay." (142 S. Ct. at 2368 (alteration in original).) Congress, not the Secretary, can decide whether the resulting DSH payments are adequate, insufficient, or even too generous. "[T]he point of the DSH provisions is not to pay hospitals the most money possible; it is instead to compensate hospitals for serving a disproportionate share of low-income patients." (*Id.* at 2367.)

*Comment*: A commenter argued that the D.C. Circuit's decision in *Allina Health Services. v. Price*, 863 F.3d 937, 939 (D.C. Cir. 2017) forecloses retroactive rulemaking here because that case held that section 1871(a)(4) of the Act applied and required notice and comment before a rule can "take effect" when a regulatory provision is not the logical outgrowth of a proposed rulemaking. The commenter states that there are two possible meanings of "take effect" in section 1871(a)(4) of the Act, and the proposed retroactive rulemaking is impermissible under either of them. According to the commenter, either this final action will be impermissibly made effective earlier than the notice-and-comment period that was required under section 1871(a)(4) of the Act, or the action will be made effective later than the required notice-and-comment period but will apply to cost reporting periods pre-dating that period in violation of section 1871(e)(1)(C) of the Act, which provides, "No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change." Relatedly, some commenters stated that retroactive rulemaking in the face of a logical outgrowth finding renders section 1871(a)(4) of the Act meaningless.

*Response*: We do not agree that the D.C. Circuit's holding in *Allina Health Services v. Price* concerning section 1871(a)(4) of the Act forecloses retroactive rulemaking here. The D.C. Circuit in *Allina I* held that the FY 2005 IPPS final rule was not a logical outgrowth of the proposed rule. *Allina I,* 746 F.3d at 1109. Section 1871(a)(4) of the Act states that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final

regulation." There was no retroactive rule challenged in *Allina Health Services v. Price* the providers in that case challenged SSI ratios that included Part C days that CMS posted after the FY 2005 IPPS final rule had been vacated. Thus, the D.C. Circuit was considering whether section 1871(a)(2) of the Act incorporates the APA's notice-and-comment exception for interpretive rules. In that context, the D.C. Circuit held that even if section 1871(a)(2) of the Act did incorporate an exception for interpretive rules (which the Supreme Court subsequently held it does not), section 1871(a)(4) of the Act required "further opportunity for public comment and a publication of the provision again as a final regulation' before HHS could re-impose the rule." 863 F.3d at 945. This final action complies with that holding as it follows a further opportunity for public comment on a proposed rule and results in publication of a final action. This action will not "take effect" until after the notice-and-comment period has closed.
Section 1871(e)(1)(C) of the Act is irrelevant here because CMS is not taking any enforcement action against providers for noncompliance with the policy adopted in this retroactive rulemaking. Instead, CMS will issue NPRs and revised NPRs, the DSH adjustments of which will be calculated pursuant to this final action. Finally, retroactive rulemaking after a failure of logical outgrowth problem does not render section 1871(a)(4) of the Act meaningless both because the retroactive rulemaking follows an opportunity for public comment, as required, and because CMS can only exercise retroactive rulemaking authority based on a finding that doing so "is necessary to comply with statutory requirements" or that failing to do so "would be contrary to the public interest." (Section 1871(e)(1)(A) of the Act.)

*Comment*: A commenter argued that promulgation of retroactive rulemakings to remedy procedural defects in a rule "make a mockery of the provisions of the [Administrative Procedure Act]," citing *Georgetown University Hospital v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987).

*Response*: In *Georgetown University Hospital*, the D.C. Circuit noted that the circuit had "previously held that the effect of invalidating an agency rule is to 'reinstat[e] the rules previously in force.'" (*Id.* at 757 (alteration in original) (emphasis omitted).) Here, there was no

rule governing the treatment of Part C days "previously in force." Moreover, that 1987 case pre-dated Congress' express grant of authority to the Secretary for retroactive rulemaking; section 1871(e) of the Act was added by section 903 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, 2376. To the extent *Empire* has not resolved the interpretive issue, the Medicare statute would require rulemaking, where it might not otherwise have been required under the APA, and the Medicare statute explicitly authorizes retroactive rulemaking.

*Comment*: Some commenters stated the retroactivity provision was intended to prevent HHS from generally applying rules retroactively by "changing the rules" and then "punishing providers," or "taking action against" them, and the provision specifically bars the agency from "reimposing" a rule on the Part C days issue on which the commenters assert HHS has lost three times in the Court of Appeals and once in the Supreme Court.

*Response*: We agree that Congress intends that HHS not generally apply a substantive change in regulations retroactively. Yet Congress did authorize retroactive rulemaking in specified circumstances. HHS's intent is not to punish providers in any way, nor do we believe this action punishes them. This action will affect final payment determinations for many providers with a new rulemaking that applies retroactively, but providers have been on notice of the Secretary's interpretation since no later than the publication of the FY 2005 IPPS final rule. While that rule eventually was vacated on notice-and-comment grounds in 2014, even then the D.C. Circuit prohibited the district court from directing the agency to calculate DSH fractions by excluding Part C days from the Medicare fraction. The Secretary has advanced the same interpretation of the statute consistently since the publication of the FY 2005 IPPS final rule. And that rule was consistent with both the agency's prior rulemaking on HMO days and its longstanding definition of "entitled" under the Medicare statute, promulgated in 1983, as meaning that "an individual meets all the requirements for Medicare benefits" (42 CFR 400.202). Providers, therefore, cannot be said to have relied on a contrary interpretation at a

minimum since FY 2005. Moreover, the D.C. Circuit has never taken issue with the Secretary's interpretation, even when it invalidated the FY 2005 IPPS final rule on procedural grounds. The Supreme Court also did not address the merits of the Secretary's interpretation when it held that the Secretary could not use Medicare fractions embodying that interpretation that were published in the absence of notice and comment rulemaking. (139 S. Ct. at 1816-17 (notice-and-comment rulemaking is required to change or establish an "avowedly 'gap'-filling policy.").) After the Supreme Court issued its *Allina II* decision, the United States District Court for the District of Columbia remanded cases presenting the Part C days issue to the agency, holding that the court had "no basis to direct the agency as to what the formula for the [DSH] recalculation should be" because "this was the aspect of the case left open by previous opinions." *In Re Allina II-Type DSH Adjustment Cases,* Misc. No. 19-0190, Dkt. 74 (Jan. 19, 2021). Paying providers in accordance with the Secretary's interpretation after remedying the procedural problems identified by the D.C. Circuit and the Supreme Court is consistent with those court decisions and permitted by section 1871(e) of the Act under these circumstances. We do not agree that paying providers consistent with our interpretation of the statute punishes providers.

*Comment*: Some commenters stated the proposed retroactive rulemaking was foreclosed by Supreme Court precedent prohibiting giving retroactive effect to statutes burdening private rights.

*Response*: We disagree that hospitals have any private right to compensation in excess of what Congress has provided for according to the best interpretation of the DSH statute. Nor was it reasonable for providers to expect that the Secretary would change his long-standing consistent interpretation of the DSH statute in the absence of any binding court ruling rejecting that interpretation on the merits.

*Comment*: Some commenters stated that the Medicare statute authorizes the Secretary to "change" a policy retroactively, but not to "establish" one, and because the Secretary concedes

he did not have a regulation in place that governed the treatment of Part C days, he cannot establish one retroactively, relying on *Bowen v. Georgetown Hosp.*, 488 U.S. 204 (1988).

*Response*: Section 1871(e) of the Act authorizes the Secretary to retroactively effect a "substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability" when the Secretary makes one or both of specified determinations. We believe this rulemaking effects a "substantive change" to the DSH regulations, which until now did not address how to treat Part C days in the DSH calculation for discharges prior to October 1, 2013. *Bowen* held that the Medicare statute's grant of authority to provide in regulation for "suitable retroactive corrective adjustments," section 1861(v)(1)(A) of the Act, did not provide authority for the promulgation of retroactive cost limit rules and neither did the Secretary's general rulemaking authority. (488 U.S. at 209.) However, *Bowen* pre-dates Congress' grant of retroactive rulemaking authority at section 1871(e) of the Act that the Secretary relies upon in this action and so its interpretation of "suitable retroactive corrective adjustments" does not speak to the interpretation of the far broader "substantive change in regulations" language in section 1871(e).

*Comment*: Some commenters stated that the August 2020 proposed rule flouts the D.C. Circuit's decision in *Northeast*. In that case, a hospital challenged the Secretary's exclusion of Part C days from the numerator of the Medicaid fraction for FYs 1999 to 2002. The court of appeals held that the Secretary could not apply his interpretation retroactively to those years. Commenters noted that the August 2020 proposed rule did not mention *Northeast* or any of the agency's prior instructions to its contractors acquiescing in that decision and subsequent resolution of cases challenging application of the FY 2005 IPPS final rule to earlier periods. Some commenters stated that *Northeast* controls the treatment of Part C days for all years prior to the prospective FY 2014 IPPS final rule. Some commenters stated that, contrary to the holding of *Northeast*, the August 2020 proposed rule "attaches new legal consequences to hospitals' treatment of low-income patients during the relevant time period."

*Response*: In *Northeast*, the D.C. Circuit observed "[i]t is well settled that an agency may not promulgate a retroactive rule absent express congressional authorization." (657 F.3d at 13.) The Secretary had not invoked the retroactive rulemaking authority in *Northeast*, and neither party brought that authority to the court's attention. That circumstance likely explains the court's statement that it was "aware of no statute that authorizes the Secretary to promulgate retroactive rules for the DSH calculations." (657 F.3d at 17.) Such a statute does exist, however, and the Secretary is invoking it here. The D.C. Circuit has held that the Medicare statute "unambiguously requires that Part C days be counted in one fraction or the other" (*Allina I*, 746 F.3d at 1108), yet does not dictate which fraction (*Northeast*, 657 F.3d at 13). And, to the extent the statute could still be said to "leave[] a 'gap' for the agency to fill" (*Allina II*, 139 S. Ct. at 1817) after the Supreme Court's clarifying decision in *Empire*, the Secretary cannot decide where to put the Part C days without first undertaking notice-and-comment rulemaking (*Id.*). In other words, because there is no rule governing the treatment of Part C days for discharges before October 1, 2013, if there is a statutory gap left to fill post-*Empire*, a rule that governs this period would be necessary even if the Secretary were to adopt the hospitals' preferred interpretation. In many cases, even a rule interpreting "entitled to benefits under part A" to exclude Part C days from the Medicare fraction (as most commenters would prefer) would itself attach new legal consequences to past discharges because the appeals were of DSH adjustments that were based on the (later-vacated) rule that embodied the Secretary's interpretation.

*Comment*: Several commenters inferred from CMS's promulgation of the FY 2014 IPPS final rule that CMS understood and impliedly conceded that it lacked authority to implement a retroactive rule.

*Response*: The prospective nature of the FY 2014 IPPS final rule did not reflect any understanding by CMS that it lacked authority to promulgate a retroactive rule. The FY 2014 IPPS final rule appeared in the **Federal Register** on August 19, 2013 (78 FR 50496), before the D.C. Circuit affirmed the vacatur of the FY 2005 IPPS final rule in *Allina I* in 2014.

Furthermore, in *Allina I*, the D.C. Circuit reversed the district court's decision insofar as it prohibited the Secretary from applying his interpretation to the *Allina I* plaintiffs' FY 2007 DSH adjustments on remand. The Secretary interpreted this aspect of the D.C. Circuit's *Allina I* decision to mean that he could proceed to calculate DSH adjustments for cost years predating the prospective FY 2014 IPPS final rule by interpreting the DSH statute's treatment of Part C days in adjudications. The Administrator issued a 46-page decision after remand in that case, concluding anew that Part C days are to be included in the Medicare fraction. However, as discussed previously, the agency's attempt to resolve this issue through adjudication was rejected in *Allina II*, and so the Secretary must instead proceed by rulemaking, to the extent there is a statutory gap to fill.

*Comment*: Some commenters stated that the August 2020 proposed rule is unfair to DSH hospitals because they have challenged the treatment of Part C days for more than a decade and now CMS is, in their view, attempting to circumvent the results of that litigation and reduce payments they believe are rightfully due to the hospitals. Similarly, many commenters expressed the opinion that it is unfair to hospitals to attempt to remedy notice and comment problems so many years after the D.C. Circuit vacated the rule; some commenters expressed that hospitals have counted on receiving additional money in DSH adjustments that would result from excluding Part C days from the Medicare fraction.

*Response*: Hospitals have pursued procedural challenges to the FY 2005 IPPS final rule, however, that rule was not vacated on logical outgrowth grounds until 2014. This action implements the subsequent directive of the Supreme Court that the Secretary establish or change a substantive legal standard concerning the treatment of Part C days only by rulemaking, if there is still a statutory gap to fill, and thus we do not agree that it is unfair for HHS to propose and finalize such a rule. We do not agree that it was reasonable for hospitals to have counted on additional reimbursement as a result of the *Allina* litigation since neither the D.C. Circuit nor the Supreme Court addressed the merits of our interpretation of "entitled to benefits under part A",

and the Secretary has consistently articulated the same interpretation for nearly twenty years. Nor do we agree that the Secretary's interpretation reduces payments that are due to hospitals. The Secretary believes this final action embodies the correct interpretation of the Medicare statute and that the alternative interpretation, that beneficiaries enrolled in Part C are not entitled to benefits under Medicare Part A, would, in many cases, result in payments in excess of what Congress intended.

*Comment*: Some commenters who disagreed that retroactive rulemaking is required here stated that if CMS nonetheless concludes that retroactive rulemaking is required, it should propose to adopt its prior practice of excluding Part C days from the Medicare fraction. A commenter stated that adoption of the August 2020 proposed rule is impermissibly retroactive, but CMS could instead simply "codify" the agency's prior agency practice and such rule would not be retroactive because, unlike the proposed interpretation, the alternative interpretation would (purportedly) not attach new legal consequences to events completed before its enactment.

*Response*: In order to exclude Part C days from the Medicare fraction, the Secretary would have to construe "entitled to benefits under part A" in the Act as excluding Part C days, and construe "not entitled to benefits under part A" as including these days. The Secretary has never so interpreted the Act. As explained previously, we believe the correct interpretation of the statute is that beneficiaries enrolled in Part C remain entitled to Part A and that the commenters' proposed interpretation would require "entitled to benefits under part A" to mean something different in the DSH statute than it does in other parts of the Medicare statue. The Supreme Court in *Empire* has foreclosed the commenters' interpretation. Even setting aside that the general prior practice was to exclude Part C days from both the Medicare fraction and the numerator of the Medicaid fraction, we do not agree that a rule that codified such a practice would not also be retroactive. Section 1871(a)(2) of the Act contemplates that policies are "establishe[d] or change[d]" only by notice and comment rulemaking. As acknowledged by the

D.C. Circuit in *Northeast*, no rule addressed the treatment of Part C days before the FY 2005 IPPS final rule, and, of course, that rule was then vacated.

*Comment*: Some commenters stated that other instances of retroactive rulemaking by CMS are distinguishable from this instance.

*Response*: The citation to other instances of retroactive rulemaking in the August 2020 proposed rule was intended to illustrate that retroactive rulemaking is not unprecedented, not because the same legal arguments justify each instance of retroactive rulemaking.

*Comment*: A commenter stated that CMS should finalize a policy of excluding Part C days from the Medicare fraction and including those days for individuals also eligible for Medicaid in the numerator of the Medicaid fraction and could lawfully do so because CMS gave the public an opportunity to comment on that proposal in the FY 2004 IPPS proposed rule.

*Response*: The Secretary believes the correct interpretation of the statute is that Part C enrollees remain entitled to benefits under Part A and for that reason will not finalize a policy of excluding such days from the Medicare fraction. Moreover, the Supreme Court's decision in *Empire* forecloses a policy of excluding Part C days from the Medicare fraction and including those days for individuals also eligible for Medicaid in the numerator of the Medicaid fraction.[16] In any event, there has been notice of and an opportunity to comment in advance on the interpretation adopted in this final action. Thus, even if the statute itself does not give rise to the substantive legal standard adopted here, thereby necessitating reliance on retroactive rulemaking authority, the public has now had an opportunity to comment on the proper interpretation of the statute, and we have considered all comments to the August 2020 proposed rule that were timely submitted as part of the development of this final action.

*Comment*: A commenter stated that because there was no valid regulation governing the treatment of Part C days between FY 2005 and FY 2014, there is a legitimate legal question of

[16] 142 S. Ct. at 2362 ("The text and context support the agency's reading: HHS has interpreted the words in those provisions to mean just what they mean throughout the Medicare statute.").

what policy governs their proper treatment, and this question should be determined by the courts in light of facts and circumstances that existed during those years. The commenter stated that CMS's proposed rule would usurp the authority of the courts.

*Response*: We agree that no valid regulation governs the treatment of Part C days between FY 2005 and FY 2014, and even before FY 2005. But CMS's interpretation of the proper treatment of Part C days has been consistent since FY 2005. The D.C. Circuit in *Allina I* held the lower court erred by directing the Secretary to include Part C days in the numerator of the Medicaid fraction, recognizing that it was an open question whether CMS could apply its interpretation retroactively through adjudication. And then the Supreme Court in *Allina II* concluded that the Secretary could only apply any gap-filling interpretation through rulemaking. Therefore, the courts have used their authority to judge the Secretary's acts, and there will be an opportunity for providers to exhaust administrative remedies and seek judicial review of the interpretation embodied in this final action, and so the role of the courts is preserved.

*Comment*: Some commenters stated that in 2012 (after the *Northeast* decision), Medicare contractors were instructed to include Part C days for dual-eligibles in the Medicaid fraction numerator for discharges on or after January 1, 1999, and before October 1, 2004. Along the same lines, some commenters noted that Medicare contractors have finalized some cost reports that were remanded under CMS Ruling 1498-R of appeals specific to the *Baystate* case (which concerned the SSI data used by CMS in calculating the Medicare fraction) with Part C days for dually eligible beneficiaries included in the Medicaid fraction numerator, while other cost reports that are the subject of appeals remanded under 1498-R will be finalized, pursuant to this final action, with Part C days included in the Medicare fraction instead. A commenter questioned what will happen for cost reports that have Part C days in the Medicaid fraction numerator but are still subject to remand or realignment where the Medicare fraction will be revised. And similarly, a commenter stated that there will be cost reports where Part C days for discharges before October 1, 2004, were already included in the Medicaid fraction but will now be finalized

with these days included in the Medicare fraction. A commenter requested that the Secretary make a distinction between discharges occurring prior to October 1, 2004, and later discharges to avoid what the commenter sees as arbitrary treatment depending on when remands or resolutions are completed and to avoid counting Part C days in both fractions.

*Response*: We appreciate the commenters' concern with treating all hospitals fairly. We do not agree that it is arbitrary or capricious to treat hospitals' Part C days differently on the basis of the timing of their appeals vis-à-vis Supreme Court and lower court decisions. The instructions to contractors that issued after the *Northeast* decision cannot control over the holding of the Supreme Court in *Allina II.* It is also not unusual for cost reports to be finalized differently from one another with respect to a legal issue depending on the outcome of litigation raising that issue and the status of a hospital's appeal at the time of a final non-appealable decision. Providers will also be able to request to have their Medicare fraction realigned to be based on their individual cost reporting periods rather than the Federal fiscal year, in accordance with the normal rules. Providers who remain dissatisfied after receiving NPRs and revised NPRs that reflect the interpretation adopted in this final action retain appeals rights and can challenge the reasonableness of the Secretary's interpretation set forth in this final action.

*Comment*: A commenter sought clarification concerning whether this action applies to pre-2000 discharges of patients enrolled in managed care organizations, such as health maintenance organizations (HMOs), or only to patients enrolled in Part C plans (first known as Medicare + Choice and later as Medicare Advantage plans). The commenter stated that the action should not be applied to pre-2000 patient discharges for days attributable to patients enrolled in Medicare HMOs authorized under section 1876 of the Act. The commenter stated that the application of this action to pre-2000 days would be inconsistent with *Baptist Medical Center v. Burwell*, 2019 WL 978957 (D.D.C. Feb. 29, 2019).

*Response*: The treatment of patients entitled to benefits under Part A and enrolled in an HMO authorized under section 1876 of the Act is outside of the scope of this rulemaking, which

applies to discharges of patients enrolled in Part C prior to FY 2014. We note, however, that section 1876 of the Act repeatedly refers to beneficiaries who are "entitled to benefits under part A," and as stated throughout this final action preamble, the statute unambiguously requires the inclusion in the Medicare fraction of patients entitled to benefits under Part A.

*Comment*: Some commenters stated that the August 2020 proposed rule would renege on the statements included in reopening notices issued between 2013 and 2015 that the CMS would adjust DSH calculations in the event of an unfavorable final, non-appealable decision in *Allina I*.

*Response*: Between 2013 and 2015 the Secretary did not yet know that neither *Allina I* nor *Allina Health Services v. Burwell,* 201 F. Supp. 3d 94 (D.D.C. 2016) (the district court case that became *Allina II*) would not lead to a final, non-appealable decision on the merits of his interpretation of "entitled to benefits under part A" to include Part C days. In 2016, the district court upheld the Secretary's interpretation in *Allina Health Services v. Burwell* but neither the D.C. Circuit nor the Supreme Court reached the merits of that interpretation.

Once this final action is effective, the Secretary will commence issuing NPRs and revised NPRs pursuant to the action, including for those NPRs previously held open.

*Comment*: Some commenters stated that the action, if it finalizes the policy proposed, will deprive hospitals with pending appeals of the Part C days issue of their right to be heard in court. Some commenters characterized a final action that embodies the proposed interpretation as a "non-action" of the Secretary and questioned how hospitals will appeal the alleged "non-action" of the Secretary, if a hospital's DSH payments calculated under the new action do not change.

*Response*: Providers with pending appeals subject to this action challenge DSH payments that were based on Medicare fractions that were issued in the absence of a valid rule addressing the Part C days issue (or, providers brought appeals to the Provider Reimbursement Review Board based on untimely NPRs and challenge Medicare fractions issued in the absence of a valid rule). The Secretary has already acquiesced in the Supreme Court's *Allina II* holding

that if the statute itself does not dictate the substantive legal standard, then such fractions could not be lawfully issued without rulemaking. Providers who have pending appeals reflecting fractions calculated in the absence of a valid rule will receive NPRs or revised NPRs reflecting DSH fractions calculated pursuant to this new final action and will have appeal rights with respect to the treatment of Part C days in the calculation of the DSH fractions contained in the NPRs or revised NPRs. Providers whose appeals of the Part C days issue have been remanded to the Secretary will likewise receive NPRs or revised NPRs reflecting fractions calculated pursuant to this new final action, with attendant appeal rights. Because NPRs and revised NPRs will reflect the application of a new DSH Part C days rule, CMS will have taken action under the new action, and the new or revised NPRs will provide hospitals with a vehicle to appeal the new final action even if the Medicare fraction or DSH payment does not change numerically.

*Comment*: Some commenters stated that the August 2020 proposed rule is unfair because it did not mention CMS Ruling 1739-R (hereinafter referred to as "the Ruling"), that the Ruling demonstrates that the outcome of the rulemaking was pre-ordained, and that the Ruling would deprive providers of appeal rights. Some commenters recommended that the final action state that the hospitals may "reinstate" any appeals remanded under the Ruling within a year after the issuance of the final action. Some commenters stated that it is unfair that the Ruling permits CMS to "reopen" properly appealed cost reports to apply this final action, but does not permit providers to cite this action as a basis for reopening closed cost reports.

*Response*: The Ruling is outside the scope of this action, but we will respond to the concern about appeal rights. The commenters misperceive the purpose and intended effect of the Ruling. The Ruling was not intended to cut off appeal rights and will not operate to do so. It was intended to promote judicial economy by announcing HHS's response to the Supreme Court's decision in *Allina II*. After the Supreme Court made clear that CMS could not resolve the avowedly gap-filling issue of whether Part C enrollees are or are not "entitled to benefits under part A" for years before FY 2014 without rulemaking, HHS issued the Ruling so that

providers would not need to continue litigating over DPP fractions that were issued in the absence of a valid rule. In other words, the point of the Ruling was to avoid wasting judicial, provider, and agency resources on cases in which the Secretary agreed that, after the Supreme Court's decision in *Allina II*, he could not defend such appeals of fractions issued in the absence of a valid regulation.

Because rulemaking would be necessary to the extent there remains a statutory gap to fill after *Empire*, and irrespective of what interpretation CMS were to adopt, the Ruling does not demonstrate that the outcome of any rulemaking was foreordained. CMS's intention was (and is) to issue new and revised NPRs consistent with this final action, in order to implement the statute and respond to the Supreme Court's decision in *Allina II.* When the Secretary's treatment of Part C days in this final action is reflected in NPRs and revised NPRs, providers, including providers whose appeals were remanded under the Ruling, will be able to challenge the agency's interpretation by appealing those NPRs and revised NPRs. While some providers have already received reopening notices and had their NPRs held open for resolution of the Part C days issue, the issuance of new NPRs and revised NPRs pursuant to remands under the Ruling are not reopenings.

*Comment*: Some commenters stated that in his petition for certiorari in *Allina II*, the Secretary said that a loss would result in significant costs, so the Secretary presumed he would have to pay these sums to providers if he lost that case.

*Response*: The Secretary's petition stated that "the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between $3 and $4 billion in reimbursement for FY2005 through FY2013." The Secretary's acknowledgement that the underlying merits issue implicated significant costs to the Medicare program neither stated nor implied that an adverse Supreme Court decision that did not touch on the merits of his interpretation would lead him to pay providers according to their preferred interpretation.

*Comment*: A commenter speculated that some hospitals may have made financial decisions, such as taking out debt through notes or bonds, or taking on construction projects, on the basis of their expectation that, after the Supreme Court's decision in *Allina II*, additional DSH funds would be forthcoming. This same commenter noted that the Secretary's November 15, 2019 motion to voluntarily remand the consolidated cases presenting the *Allina* issue in *In Re Allina II-Type DSH Adjustment Cases*, Misc. No. 19-0190 (D.D.C), stated that voluntary remand would give the providers that had appeals pending before the district court the "functional equivalent of a victory on the merits without any need to litigate the matter"; this commenter interpreted this statement to mean that CMS was intending to pay additional DSH funds after recalculating Medicare fractions to exclude Part C days.

*Response*: No hospital commented that it had made financial decisions in reliance on the expectation of additional payment after the Supreme Court's decision, based on the expected exclusion of Part C days from the Medicare fraction for years with open appeals. Nor would such reliance have been reasonable, as the reasonableness of the Secretary's interpretation was not the issue before the Supreme Court in *Allina II*, nor did it opine on this issue.

The Secretary's statement in district court that a remand was the functional equivalent of a victory for plaintiff hospitals did not imply that the Secretary intended to pay plaintiffs according to their preferred interpretation of the DSH statute. The Secretary's November 15, 2019 motion to voluntarily remand the consolidated cases that presented the *Allina* issue stated accurately that a remand would give the plaintiff hospitals all they could achieve in a victory in their challenge to the procedural defects of the Secretary's calculation of Medicare fractions in the absence of a validly promulgated rule: namely, a remand for further proceedings consistent with the Supreme Court's decision. In other words, there was no need to litigate the issue of whether notice-and-comment rulemaking was necessary for deciding the treatment of Part C days because the cases were all controlled by the Supreme Court's decision in *Allina II*. Moreover, the Secretary disclosed in his November 15, 2019 motion to dismiss that he was

contemplating retroactive rulemaking. And, as noted, the Supreme Court had not addressed the reasonableness of the Secretary's interpretation of the DSH statute, and *Allina II* pre-dated *Empire* wherein the Court agreed with the Secretary's interpretation of what it means to be "entitled to benefits under part A" of the Act.

*Comment*: Some commenters, relying on the Ninth Circuit's *Empire* decision, stated that the Secretary's interpretation of "entitled to benefits under part A" impermissibly treats "entitled" and "eligible" as synonymous. According to these commenters, beneficiaries are "entitled" to Part A benefits only on covered days but are eligible for Medicaid on days for which Medicaid does not pay. Therefore, these commenters conclude, the Secretary errs in treating a day for which Medicare Part A does not pay as a day for which that patient is entitled to benefits under Part A.

*Response*: Whether exhausted benefit days and Medicare Secondary Pay days attributable to Medicare beneficiaries should be included in the Medicare fraction even though Medicare has not paid for them is beyond the scope of this action and has been resolved by the Supreme Court in *Empire*. As the Secretary explained in his briefing in that case, Congress's use in the Medicare and Medicaid fractions of "entitled" and "eligible" in referring to the Medicare and Medicaid programs, respectively, merely reflects Congress's usage of different terminology in the underlying Medicare and Medicaid statutes. (*Northeast*, 657 F.3d at 12.) The Supreme Court agreed with this reading of the statute. (*Empire*, 142 S. Ct. at 2363 n.3.) Moreover, as noted previously, CMS has always considered Part C days to be covered days.

*Comment*: Some commenters stated that CMS is mistaken that the Supreme Court's holding in *Allina II* requires notice-and-comment rulemaking to resolve fiscal years before the FY 2014 final rule became effective. They state that the Court held only that "the rule" before it was invalid because it did not go through notice-and-comment rulemaking. They further assert that because the D.C. Circuit in *Allina I* held that CMS could resolve the treatment of Part C days in the DSH fraction by adjudication, and CMS agreed with this in its

briefing in *Allina II*, CMS could now proceed by adjudication, and retroactive rulemaking is therefore not required.

*Response*: We disagree that there was a rule at issue in *Allina II*. Rather, plaintiffs in that case challenged the publication of Medicare fractions on CMS's website, fractions that CMS had expected could be used in DSH calculations, then appealed and, under *Allina I*, resolved by adjudication. However, the Supreme Court in *Allina II* held that publishing of the Medicare fractions was "at least a 'statement of policy' because it 'le[t] the public know [the agency's] current . . . adjudicatory approach' to a critical question involved in calculating payments for thousands of hospitals nationwide." (139 S. Ct. at 1810 (alterations in original).) The Court held that, because that policy established an avowedly gap-filling substantive legal standard, the Medicare statute required notice-and-comment rulemaking.

The Secretary does not see an adjudicatory approach to the treatment of Part C days that would be consistent with the Supreme Court's holding in *Allina II* (at least to the extent that a statutory gap remains after *Empire*). Medicare fractions necessarily include or exclude Part C days. Whether Part C enrollees are "entitled to benefits under part A," or are not so entitled, is a legal question that does not turn on facts unique to any particular hospital. Thus, to resolve this issue by adjudication, hospitals would appeal fractions that, just as in *Allina II*, would necessarily already reflect a policy establishing the substantive legal standard of which DPP fraction includes Part C days and would end in final agency decisions that reflect the same policy in each case.

*Comment*: Some commenters stated that their Medicare Administrative Contractors (MACs) are still issuing NPRs applying the vacated policy; thus, they opine, the Secretary is being disingenuous in claiming that retroactive rulemaking is necessary to calculate fractions. Similarly, some commenters stated that because CMS issued fractions before FY 2005 without a regulation governing the treatment of Part C days, CMS knows that it can calculate fractions in the absence of a rule.

*Response*: After the Supreme Court's decision in *Allina II*, in April 2020 the Secretary instructed MACs to stop issuing NPRs calculating DSH fractions until promulgation of a new final rulemaking. That some contractors issued NPRs before this instruction or contrary to the instruction does not demonstrate that the Secretary is being disingenuous. Where providers have challenged the treatment of Part C days in NPRs prior to this final action, the Secretary has sought to have these cases remanded for recalculation under the final action. While it is operationally possible to calculate DSH fractions in the absence of a new rulemaking, any such fractions must necessarily treat Part C enrollees as entitled to benefits under Part A or as not-so entitled. After the Supreme Court's ruling in *Allina II*, establishing or changing a policy concerning Part C days in the absence of rulemaking is impermissible, to the extent there is a gap to fill in the statute. Whether calculating DSH fractions is feasible as a practical matter and whether such calculations are legally permissible (either procedurally or as a matter of interpretation) are distinct questions.

*Comment*: Some commenters stated that CMS did not collect information about Part C days from non-teaching hospitals prior to October 1, 2006, and therefore cannot "enforce" the August 2020 proposed rule as written; some of these commenters refer to Transmittal 1311 issued July 29, 2007, which instructed providers to submit "no-pay" claims for Medicare Advantage days because Medicare Advantage plans would no longer be required to submit "encounter days" for inclusion in the Medicare Provider and Analysis Review (MedPAR) file. Some of these comments argue that because Transmittal 1311 was not itself promulgated by regulation it is invalid under the Supreme Court's decision in *Allina II*. Some commenters described various change requests relating to data for Part C days that CMS issued to hospitals over the years and speculated as to the significance of the timing of those requests. Some stated that, because CMS has different data for teaching hospitals than non-teaching hospitals it will necessarily apply different "methodologies" to these different types of hospitals (teaching hospitals and other hospitals), whereas the statute does not provide for different treatment. A

commenter suggested that CMS should choose a method of treating Part C days for which the Part C data is available for all hospitals for all discharges before the FY 2014 IPPS final rule became effective on October 1, 2013; this commenter stated that this would mean excluding Part C days from the Medicare fraction and including them (for individuals also eligible for Medicaid) in the Medicaid fraction numerator. A commenter stated that it would be arbitrary and capricious and contrary to the public interest for CMS to apply the August 2020 proposed rule to all hospitals for all discharges prior to October 1, 2013, when it does not have necessary data to include Part C days for all hospitals, and some hospitals will lack the ability to supply this data.

*Response*: Transmittal 1311 is outside the scope of this action. At least some of these commenters appear to believe, mistakenly, that CMS will require hospitals to submit information about their Part C days for periods prior to October 1, 2006. This action concerns the Secretary's interpretation of "entitled to benefits under part A" as it relates to the treatment of Part C days. That interpretation is logically distinct from any operational issues with whether or not CMS is able to include all such days in the Medicare fraction for any given hospital. We do not agree that if Part C days are not included in a hospital's Medicare fraction because CMS and the hospital do not have the necessary data that this means that CMS is applying a different methodology to that hospital than it applies to a hospital for which it does have such data. Nor do we agree that the Secretary's interpretation of the statute should be determined by what data is readily available for all or most hospitals.

After considering the comments received, we are finalizing our proposal that a patient enrolled in an MA plan remains entitled to benefits under Medicare Part A and will be counted in the Medicare fraction of the DPP and not counted in the numerator of the Medicaid fraction.

## III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review

by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

**IV. Regulatory Impact Analysis**

A. Statement of Need

This final action is necessary to create a policy governing the treatment of days associated with beneficiaries enrolled in Medicare Part C for discharges occurring prior to October 1, 2013, for the purposes of determining additional Medicare payments to subsection (d) hospitals under section 1886(d)(5)(F) of the Act.

B. Overall Impact

We have examined the impact of this action as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) as amended by Executive Order 14094 (April 6, 2023), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended recently by Executive Order 14094, defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering

the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866.

The discussion accompanying our proposal along with this Regulatory Impact Analysis (RIA) demonstrate that this final action has been analyzed consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. We note that Medicare DSH payments affect a substantial number of small rural hospitals, as well as other classes of hospitals, and the effect of Medicare DSH payments on some hospitals is significant.

An RIA must be prepared for major rules that are subject to Section 3(f)(1) of Executive Order 12866 (effect on economy of $200 million or more in any 1 year). This action is subject to Section 3(f)(1) of Executive Order 12866 and also meets the definition in 5 U.S.C. 804(2) (Congressional Review Act). Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the action.

C. Detailed Economic Analysis

In the August 2020 proposed rule (85 FR 47726), we explained that DSH payments made under our proposed policy, which we are finalizing here, would not differ from hospitals' historical DSH payments. We also stated that Medicare DSH payments have already been made under the policy reflected in the proposal (prior to the previous rule which governed the treatment of these days having been vacated by the Court of Appeals, which was affirmed by the Supreme Court's decision). Therefore, the effect of the August 2020 proposed rule being finalized here would be to avoid the consequences of legal ambiguity created by the absence of any properly promulgated regulation that would otherwise continue into the future; the resulting costs, benefits, and transfer impacts are thus highly uncertain. In other words, given that there is currently no regulation governing the treatment of Part C days for the period before FY 2014, it

is not clear what to compare an estimate of DSH payments under the policy we are finalizing in order to determine the effect of this policy on DSH payments during that time period.

In the August 2020 proposed rule (85 FR 47726 through 47727), we stated that there are multiple possible trajectories whereby agency actions could be made consistent with the Supreme Court's ruling requiring notice-and-comment rulemaking. The proposed (and now final) policy provides one such trajectory, and we stated that DSH payments made under the proposed policy would not differ from hospitals' historical DSH payments; as such, this comparison between DSH payments under our proposed policy and hospitals' historical DSH payments quantifies one point within the relevant uncertainty range of potential costs, benefits, and transfer impacts. In order to explore another possible trajectory (and thus to quantify an additional point within the relevant uncertainty range), we also discussed our consideration of an alternative approach that excluded days associated with patients enrolled in Medicare Part C from the calculation of the Medicare fraction and included them in the numerator of the Medicaid fraction (for those patients who are dually eligible). In addition, we explained that we were not proposing such a policy because we continue to believe, as we stated in the preamble to the FY 2014 IPPS final rule (78 FR 50614 and 50615) and have consistently expressed since the issuance of the FY 2005 IPPS final rule, that individuals enrolled in MA plans are "entitled to benefits under part A" as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi) of the Act. However, in conjunction with the August 2020 proposed rule, we created a public use data file in order to facilitate public comment and analysis of our proposal and the alternative approach. This file was made available in the Downloads section of the Disproportionate Share Hospital webpage on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh. The file contained an illustrative model at the hospital level of the potential effect on the DSH adjustment of excluding days associated with patients enrolled in Medicare Part C from the Medicare fraction and including them in the numerator of the Medicaid fraction (for those patients who are dually eligible).

Based on this illustrative model, in the August 2020 proposed rule we stated that under the alternative approach, most hospitals' Medicare DSH payments would increase relative to their historical Medicare DSH payments; however, some hospitals' Medicare DSH payments would decrease or not change. As discussed in the proposed rule (87 FR 47727), in aggregate, the modelled Medicare DSH payments under the alternative approach would increase by 6 percent relative to the historical Medicare DSH payments, which for the hospitals represented in the model meant approximately a net $0.6 billion annualized increase for their longest cost reporting period ending between January 1, 2013, and December 31, 2013. In that same proposed rule, we stated that these estimates were for illustrative purposes and involved modelling assumptions (for example, use of a proxy for the Medicaid days associated with patients enrolled in Medicare Part C, as described previously), which may differ from actual calculations that would be done during cost report review and settlement processes by contractors if such a policy were adopted. These expenditures (or, as regards payments already made for past years, the avoidance of potentially necessary reimbursements from providers to the Trust Fund) would be classified as transfers to Medicare providers. In addition, we sought comments on this illustrative model of the alternative approach and the assumptions used in this analysis. For additional details on the illustrative model, we refer readers to the August 2020 proposed rule (85 FR 47726 through 47727).

*Comment*: We received many comments about the financial impact of the August 2020 proposed rule and the modeling of the alternative approach. Many commenters stated that the August 2020 proposed rule did not attempt to address what the loss in DSH payments associated with the agency's retroactive proposal would mean to safety net hospitals. Several commenters estimated that for 2004 to 2013 there would be a multibillion dollar difference under the proposed policy compared to the alternative approach.

Many commenters stated that the alternative approach underestimated the impact on hospitals. Many of these commenters used their own data to argue that the estimated impact of

the proposed rule was higher than the amount reflected under the alternative approach. Some commenters stated that CMS's calculations under the alternative approach using the illustrative model (that is, removing Part C days from the Medicare fraction and including in the Medicaid fraction days associated with patients enrolled in Medicare Part C who were also eligible for SSI as a proxy for counting Medicaid eligible days) are "suspect" due to issues with the CMS's data file, such as the exclusion of Medicaid patients. These commenters suggested that CMS should have validated data by requesting from providers the patient eligibility information.

Some commenters disagreed with the August 2020 proposed rule's description of the summary of costs and benefits described as "highly uncertain" because the commenters stated CMS has actual hospital data for October 1, 2005, through September 30, 2013, and they believe that data should have been used by CMS to calculate "more accurate" estimates, at least for discharges after September 30, 2005, instead of using a proxy as CMS did with its alternative model of using days associated with patients enrolled in Medicare Part C who were also eligible for SSI benefits as a proxy to count Medicaid days for FY 2013. Commenters stated that over the years CMS has been inconsistent in its estimates of the financial impact of including Part C days in the Medicare fraction and excluding them from the numerator of the Medicaid fraction. Some commenters stated that CMS ought to have sought patient details concerning Part C days from its contractors to account in its alternative calculations for Part C beneficiaries who are eligible for Medicaid but who do not receive SSI benefits. In addition, some commenters stated that CMS's modeling of the alternative approach failed to account for the impact on capital DSH payments, and another commenter indicated that the model did not include hospitals that do not currently qualify for DSH payments, but would qualify for DSH under the alternative approach.

Some commenters faulted CMS's proxy modeling assumption because it did not account for beneficiaries enrolled in Part C who receive SSI but who are not eligible for Medicaid. Specifically, commenters expressed that CMS's estimates exclude the very large number of Medicaid patients who are not receiving SSI benefits, thereby understating the effect of the issue

on the Medicaid fraction. In addition, some commenters stated that it was unreasonable for CMS to use only 2013 data or any proxy at all, and that providers did not have the information about financial impact they needed to comment meaningfully.

*Response*: We thank the commenters for their input. Regarding the comments on the financial impact of the proposal, we stated in the August 2020 proposed rule that the DSH payments under the proposed policy will not differ from historical payments for years after FY 2005 for most hospitals because CMS has made payments under the same interpretation, an interpretation which has never been substantively struck down. Many commenters compared the difference in the estimated DSH payments between the proposal and alternative approach using the hospitals' own estimates. Commenters' ability to do so overwhelmingly shows that many commenters were able to meaningfully engage with the August 2020 proposed rule's policy proposal and alternative approach model.

There has been more than a decade of litigation over the treatment of Part C days in DSH calculations, and it is widely understood by DSH hospitals, and the Secretary has acknowledged, that the financial impact of the Secretary's interpretation of "entitled to benefits under part A" to include Part C days in the Medicare fraction as compared with excluding them, is significant. While hospitals may argue whether the Secretary has over- or under-stated that number in the proxy described in the August 2020 proposed rule's alternative approach, by the time the August 2020 proposed rule was published hospitals had years of experience of the financial impact of the Secretary's interpretation, as the Secretary has been applying his policy to DSH adjustments for years.[17]

Regarding the commenters who stated CMS should have used alternative data sources and/or hospitals' patient level data and/or different assumptions for the illustrative model of the

[17] FY 2013 IPPS/LTCH PPS final rule (78 FR 50614) (explaining that the policy was adopted in 2004 and CMS regulations were amended in 2007); *id.* at 50620 (noting explicit instructions in 2007 and 2009 that hospitals submit information for Part C patients after the agency discovered that hospitals were not submitting the necessary information).

alternative approach, in the August 2020 proposed rule we stated that these estimates are for illustrative purposes and involve modelling assumptions (for example, use of a proxy for the Medicaid days associated with patients enrolled in Medicare Part C, as described previously) which may differ from actual calculations that would be done during cost report review and settlement processes by contractors if such a policy were adopted (85 FR 47727). In other words, the proxy assumption and alternative approach model were intended to approximate the potential impact of the proposed interpretation and facilitate comment, rather than to reflect actual payment calculations.

We note that, under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposal or a description of the subjects and issues involved. We disagree with the commenters' assertion the August 2020 proposed rule did not provide an opportunity to meaningfully comment on the financial impact of the proposed policy. The August 2020 proposed rule did include a detailed discussion of our proposed policy and alternative approach to facilitate comments. Furthermore, as discussed, many commenters were able to meaningfully engage with the policy proposal and alternative approach, as evidenced by the analyses they provided in their comments, including comparisons of the difference in estimated DSH payments between the proposal and alternative approach using hospitals' own estimates. Accordingly, we believe interested parties were able to meaningfully comment on our proposed policy and the alternative approach.

In addition, the financial impact of the interpretation of "entitled to benefits under part A" is not legally relevant to the substance of CMS's interpretation of that statutory clause in relation to the treatment of Part C days in the DPP calculation. Whether that clause is best interpreted to include Part C days has never turned on the financial impact of that interpretation in comparison with the impact of treating Part C enrollees as not entitled to benefits under Part A. That many hospitals would enjoy higher DSH payments if CMS adopted the interpretation that Part C enrollees are not "entitled to benefits under part A" does not show that Congress would have

agreed with that interpretation.[18] Information from CMS contractors about Part C enrollees dually eligible for Medicaid would not resolve the interpretive question of whether Part C enrollees are or are not "entitled to benefits under part A."

*Comment*: A commenter stated that the August 2020 proposed rule would disproportionately affect rural hospitals because such hospitals are struggling more than urban hospitals due to the COVID-19 pandemic. The commenter considers the statement in the August 2020 proposed rule that there would not be additional costs or benefits for small rural hospitals to be arbitrary and capricious because, in the commenter's view, the DSH payments received by these hospitals were improperly calculated for these and other hospitals under a vacated rule.

*Response*: In the August 2020 proposed rule the Secretary acknowledged that Medicare DSH payments generally affect a substantial number of small rural hospitals, as well as other hospitals, and the effect of DSH payments on some hospitals is significant (85 FR 47726). (We note approximately 500 rural hospitals with less than 100 beds are eligible for Medicare DSH payments.) The August 2020 proposed rule stated that a regulatory impact analysis under section 1102(b) of the Act was nonetheless not necessary because the Secretary had determined that adoption of the August 2020 proposed rule would not impose "additional costs or benefits" for small rural hospitals "relative to Medicare DSH payments that have already been made" because the DSH payments for these hospitals (like others) have generally already been calculated according to the proposed interpretation. Nonetheless, we included a discussion with a regulatory impact analysis in the interest of public transparency.

We do not agree that the DSH payments already calculated for such hospitals reflect an unreasonable interpretation. In the August 2020 proposed rule, we proposed to adopt an interpretation of the statutory language "entitled to benefits under part A" in section 1886(d)(5)(F)(vi)(I) to include Part C enrollees. We do not agree that the financial impact of

[18] *See Empire*, 142 S. Ct. at 2367 ("[T]he point of the DSH provisions is not to pay hospitals the most money possible; it is instead to compensate hospitals for serving a disproportionate share of low-income patients.").

COVID-19 on hospitals generally or on rural hospitals specifically is relevant to the proper interpretation of that phrase as the statute long pre-dates the pandemic.

D. Alternative Considered

In the August 2020 proposed rule, we considered as an alternative to our proposal excluding days associated with patients enrolled in Medicare Part C from the calculation of the Medicare fraction and including them in the calculation of the Medicaid fraction for dually eligible beneficiaries. However, in the August 2020 proposed rule, we stated that we were not proposing such a policy because we continue to believe, as we stated in the preamble to the FY 2014 IPPS final rule (78 FR 50614 and 50615) and have consistently expressed since the issuance of the FY 2005 IPPS final rule, that individuals enrolled in MA plans are "entitled to benefits under part A" as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi) of the Act.

In the August 2020 proposed rule, we sought comments on our proposed approach as well as on the alternative approach. After consideration of those comments, in this final action we are adopting the same policy of including MA patient days in the Medicare fraction that was prospectively adopted in the FY 2014 IPPS final rule and applying this policy retroactively to any cost reports that remain open for cost reporting periods starting before October 1, 2013. This final action also provides descriptions of the statutory provisions that are addressed, identifies the finalized policy, and presents rationales for our decisions and, where relevant, alternatives that were considered.

E. Accounting Statement

As required by OMB Circular A–4, in the following Table 1 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final action as they relate to hospitals receiving Medicare DSH payments. It is not clear what to compare an estimate of DSH payments under our final policy. Therefore, consistent with the proposed rule, this table provides our estimate of the change in Medicare

DSH payments to hospitals as a result of the policy finalized in this action based on a range of potential expenditures. All expenditures are classified as transfers to Medicare providers.

**TABLE 1.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED MEDICARE DSH EXPENDITURES PRIOR TO FY 2014**

| Category | Transfers |
|---|---|
| Annualized Monetized Transfers | $0 - $0.6 billion |
| From Whom to Whom | Federal Government to Hospitals Receiving Medicare DSH Payments |

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either because they are nonprofit organizations or because they meet the Small Business Administration (SBA) definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that with the adoption of this policy there will not be any additional costs or benefits relative to Medicare DSH payments that have already been made. Therefore,

this final action will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that with the adoption of this policy there will not be any additional costs or benefits for small rural hospitals relative to Medicare DSH payments that have already been made to these hospitals. Therefore, this final action would not have a significant impact on the operations of a substantial number of small rural hospitals.

## G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This final action will have no unfunded mandate effect on state, local, or tribal governments or on the private sector.

## H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this action does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

## I. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final action was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 23, 2023.

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**Xavier Becerra,**

Secretary,

Department of Health and Human Services.

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