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September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–1695–P, Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; Proposed Rule (Vol. 83, No. 147), July 31, 2018.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2019.

The AHA is deeply disappointed in certain proposals that CMS has chosen to set forth in this rule, which run afoul of the law and rely on the most cursory of analyses and policy rationales. Taken together, they would have a chilling effect on beneficiary access to care and new technologies, while also dramatically increasing regulatory burden. Specifically, the AHA strongly opposes CMS's proposals to:

- **Reduce payment for the hospital outpatient clinic visit in excepted off-campus provider-based departments (PBDs) to the “physician fee schedule (PFS)-equivalent” rate of 40 percent of the OPPS rate;**
- **Reduce payment for services from expanded clinical families furnished in excepted off-campus PBDs to 40 percent of the OPPS rate; and**
- **Continue the current policy that pays for separately payable drugs acquired through the 340B program at the rate of average sales price (ASP) minus 22.5 percent and expand this payment cut to nonexcepted PBDs.**

First, we strongly oppose CMS’s proposal to pay for clinic visits furnished in excepted off-campus PBDs at the PFS-equivalent rate of 40 percent of the OPPS rate and urge the agency to withdraw it from consideration. CMS lacks statutory authority to reduce payments to excepted PBDs to the level of nonexcepted PBDs, particularly in a non-budget-neutral manner. Congress expressly chose *not* to confer on CMS authority to reimburse excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs – it clearly intended for there to be a material distinction in payment rates between excepted and nonexcepted PBDs. **In addition, the agency’s proposal is arbitrary and capricious – CMS has no basis to conclude that PBD services have increased unnecessarily, which is the predicate finding necessary to support its proposed policy.** Indeed, the agency’s so-called analysis that identifies “unnecessary” shifting of services from physician offices to PBDs completely ignores substantially impactful factors outside of hospitals’ control that also result in increases in OPPS volume and expenditures. This includes things such as the impact of other Medicare policies that increase the volume of services in PBDs (for example, the “two-midnight” policy) and the skyrocketing prices of drugs. Cuts of the magnitude proposed in the clinic visit policy would be excessive, harmful and endanger the critical role that hospital outpatient departments (HOPDs) play in their communities, including providing convenient access to care for the most vulnerable beneficiaries, including the sickest, most medically complex patients.

Second, we strongly oppose and urge the withdrawal of CMS’s proposed policy to pay for services from expanded clinical families that are furnished in excepted off-campus PBDs at the PFS-equivalent rate. This proposal is similarly arbitrary and capricious – it lacks statutory authority and relies on inaccurate speculation regarding Congress’s legislative intent. The agency’s proposed policy runs counter to and undermines the Administration’s stated goal of reducing regulatory burden. Specifically, compliance with expanded clinical families policy would impose nearly insurmountable operational challenges and regulatory burden for hospitals. Also, it would have a negative effect on beneficiaries by reducing their access to care. Moreover, it would hamper innovation and the ability of hospitals to meet the changing needs of their communities.

Finally, CMS should reverse its current policy that pays for separately payable, non-pass-through drugs acquired through the 340B program at the rate of the ASP minus 22.5 percent. Moreover, we urge the agency to withdraw its proposal to expand this payment cut to nonexcepted PBDs. We believe the agency has proposed (or implemented) policies that are contrary to the statutory authority to impose such drastic reductions in the payment rate for 340B drugs, effectively eviscerating the benefits of the program.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

American Hospital Association (AHA) Detailed Comments on the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule for Calendar Year (CY) 2019

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PROPOSED REDUCTION IN PAYMENT FOR HOSPITAL OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS (PBDs)

Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, with the exception of dedicated emergency department (ED) services, services furnished in off-campus PBDs that began billing under the OPSS on or after Nov. 2, 2015 (BiBA's date of enactment), or that do not meet the 21st Century Cures "mid-build" exception (referred to as "nonexcepted" services by CMS), will no longer be paid under the OPSS. Instead, these nonexcepted services are required to be paid under another applicable Part B payment system. Services furnished in off-campus PBDs that were billing under the OPSS before Nov. 2, 2015 or that met the mid-build exception are not subject to the site-neutral payment reductions and are referred to by CMS as "excepted". In the CY 2019 physician fee schedule (PFS) proposed rule, the agency continues to identify the PFS as the applicable payment system for most nonexcepted services and proposes to set payment at 40 percent of the OPSS rate for these services.

In the CY 2019 OPSS proposed rule, the Centers for Medicare & Medicaid Services (CMS) describes "unnecessary" increases in the volume of hospital outpatient clinic visits in hospital PBDs and, citing its authority under section 1833(t)(2)(F)¹ of the Social Security Act (SSA), proposes to pay for clinic visits furnished in excepted off-campus PBDs at the "PFS-equivalent" rate of 40 percent of the OPSS rate. CMS further proposes to implement this proposal in a non-budget neutral manner, which the agency estimates would result in a CY 2019 reduction of \$760 million in hospital payment under the OPSS.

That AHA strongly opposes CMS's proposal to reduce payment for clinic visits furnished by excepted PBDs and urges the agency to withdraw it. In short:

- **The clinic visit proposal is arbitrary and capricious. CMS lacks statutory authority to reduce payments to excepted PBDs and has no basis for its assertion that outpatient department (OPD) services have increased unnecessarily.**
- **CMS's proposal to implement the clinic visit policy in a non-budget neutral manner is also contrary to the plain language of the statute.**
- **The proposal is based on unsupported assertions of "unnecessary" increases in volume and other flawed assumptions. It ignores the many factors outside the hospitals' control that also result in increased**

¹ "(2) SYSTEM REQUIREMENTS.— Under the payment system—... (F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services."

outpatient volume, including those Medicare policies that are intended to promote, or otherwise incentivize, increases in outpatient services.

- **Making cuts to hospital reimbursement of the magnitude proposed would be excessive and harmful; it would endanger the critical role that PBDs play in their communities, including providing local access to care for the most vulnerable beneficiaries.**

The Proposed Reduction in Payment for Clinic Visits Furnished by Excepted PBDs Is Unlawful. **CMS's proposal to reduce OPPS payments for certain clinic visit services furnished at off-campus PBDs that are excepted from section 1833(t)(21) of the SSA is unlawful. Simply put, CMS lacks statutory authority to reduce payments to excepted PBDs to the level of nonexcepted PBDs.** Specifically, the proposed payment reduction is unlawful because Congress expressly chose *not* to confer on CMS the authority to reimburse excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs. That is, Congress intended for there to be a material distinction in payment rates between excepted and nonexcepted PBDs, accounting for why Congress created an exception that statutorily grandfathers certain PBDs from being subject to the payment changes under section 603 of the BiBA.²

Section 603 excepts certain grandfathered PBDs from the payment system change applicable to nonexcepted PBDs. The statutory exception applies to off-campus PBDs that were “billing under [OPPS] with respect to covered OPD services furnished prior to the date of the enactment of” Section 603.³ Congress’s purpose in creating this exception was “effectively [to] grandfather[] any off-campus PBD ... that was billing outpatient services before ... Nov. 2, 2015,” and thereby to prevent such excepted PBDs from being subject to the lower payment rates applicable to “new” PBDs (i.e., PBDs not billing for services until after Nov. 2, 2015).⁴

In proposing to reduce payment to these excepted PBDs, CMS is ignoring the repeated, post-enactment warnings from Congress that it did not intend *grandfathered* off-campus PBDs to be subject to payment reductions in furtherance of a site-neutral payment policy.⁵ **Even more significantly, CMS also is ignoring the express and statutorily-**

² Bipartisan Budget Act of 2015, Pub. L. No. 114-74 § 603, 129 Stat. 584, 598; see *City of San Jose v. Office of the Comm’r of Baseball*, 776 F.3d 686, 691 (9th Cir. 2015) (explaining that, “when Congress specifically legislates in a field and explicitly exempts an issue from that legislation, [courts’] ability to infer congressional intent to leave that issue undisturbed is at its apex”); see also U.S. House of Representatives, *Bipartisan Budget Act of 2015: Section-by-Section Summary* 6 (Oct. 27, 2015) (explaining that, under section 603, “[a]ny PBD [hospital outpatient department] executing a provider agreement after the date of enactment [of section 603], would not be eligible for reimbursements from CMS’s Outpatient Prospective Payment System . . . [and] would [instead] be eligible for reimbursements from either the Ambulatory Surgical Center . . . [payment system] or the Medicare Physician Fee Schedule”—both of which have lower rates of payment relative to OPPS).

³ SSA § 1833(t)(21)(B)(ii).

⁴ H.R. Rep. No. 114-604, at 10 (2016) (Conf. Rep.). This conference report relates to H.R.5273, whose proposed section 603 exceptions were later incorporated into the 21st Century Cures Act, which was enacted in December 2016.

⁵ See, e.g., Letter to Andrew M. Slavitt, Acting Administrator, CMS, from 235 members of the House of Representatives and 51 Senators (May 24, 2016) (letter signed by a majority of both Houses of Congress explaining

mandated grandfathering exception created by section 603. CMS's proposal would eliminate the statutory exception because payment to excepted and not-excepted off-campus PBDs would be the same.

Allowing CMS to render the statutory exception a legal nullity would violate a fundamental tenet of statutory construction requiring, whenever possible, that statutes be “construed so that effect is given to all [] provisions, so that no part will be inoperative or superfluous, void or insignificant.”⁶ It also would be clearly in excess of CMS's statutory authority. CMS would be abrogating an exception created by *Congress*—and agencies lack the authority to “pre-empt the validly enacted legislation of a sovereign State.”⁷

CMS does not have the authority to implement the Medicare Act in a fashion that eliminates an exception that was expressly established by statute.⁸ When it enacted section 603, Congress made a clear policy choice that excepted PBDs would *not* be subject to the same site-neutrality policies that apply to nonexcepted PBDs. CMS's proposal *disagrees with and seeks to overturn* the policy choice made by Congress. But it is well established that “federal agencies may not ignore statutory mandates or prohibitions merely because of policy disagreements with Congress.”⁹

Congress's decision not to alter payment to excepted PBD under section 603 is clear; it is further supported by the additional statutory exceptions to section 1833(t)(21)(B) that were added by the 21st Century Cures Act. Indeed, the exceptions subsequently enacted by Congress were *premised* on the idea that excepted off-campus PBDs would be protected from any payment system change applied to nonexcepted off-campus PBDs. As explained in the bill that first introduced the exceptions, Congress was “concern[ed] with [s]ection 603 ... because it *did not exclude from the new payment rates* those off-campus [hospital outpatient departments] that were mid-build before the enactment and inadvertently included ‘cancer hospitals’” and other OPPS-exempt hospitals.¹⁰

Both the original exception in section 603 and subsequent exceptions demonstrate that CMS's proposal is *ultra vires* – it goes beyond the scope of the agency's authority.

that section 603 is intended to “establish[] lower payment levels for *new* off-campus hospital patient departments” and urging CMS *not* to adopt various interpretations that would “trigger payment reductions under [s]ection 603” for facilities that “were billing under the OPPS prior to November 2, 2015”) (emphasis added); Letter to Members of the Health Care Community from the Committee on Energy Commerce (Feb. 5, 2016) (explaining that section 603 “established a site neutral payment policy for *newly-acquired*, provider-based, off-campus hospital outpatient departments) (emphasis added).

⁶ *Hibbs v. Winn*, 542 U.S. 88, 101 (2004).

⁷ *Louisiana Pub. Servs. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

⁸ *Whitman v. American Trucking Ass'n*, 531 U.S. 457, 485 (2001) (“[An agency] may not construe the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion.”).

⁹ *In re Aiken Cty.*, 725 F.3d 255, 260 (D.C. Cir. 2013).

¹⁰ H.R. Rep. No. 114-604, at 10 (2016) (Conf. Rep.) (emphasis added).

The Proposed Reduction in Payment for Clinic Visits Furnished by Excepted PBDs is Also Arbitrary and Capricious. **CMS’s proposed reduction in payment to excepted PBDs is also arbitrary and capricious for a number of reasons.** First, the proposed reduction is based on an impermissible interpretation of the statute. SSA section 1833(t)(2)(F) states that CMS “shall develop a method for controlling unnecessary increases in the volume of covered [OPD] services.” **In the proposed rule, CMS explains its view that reducing payment to excepted off-campus PBDs to equal the lower payment amounts received by nonexcepted off-campus PBDs is a “method” for controlling unnecessary increases in the volume of covered OPD services. We disagree.**

Section 1833(t)(2)(F) is not a basis of statutory authority to do *anything other than* “develop a *method* for controlling unnecessary increases in the volume of covered OPD services.”¹¹ But the plain meaning of a “method” is that it is a “way of doing things” or, in other words, a “*plan*.”¹² All section 1833(t)(2)(F) does is mandate that CMS devise a plan for controlling unnecessary increases in volume *pursuant to the authority conferred by the other provisions of section 1833(t)*.

First, if Congress had intended section 1833(t)(2)(F) to confer direct authority on CMS to modify OPPS payment rates for specific services, it would have said so expressly—just as it did in section 1833(t)(2)(E). Section 1833(t)(2)(E) *expressly* says that CMS may “adjust” outlier payments, transitional add-on payments, and implement other payment adjustments as necessary to ensure equitable payments. There is no reason to think that Congress would *implicitly* confer authority to modify payment rates in section 1833(t)(2)(F) where, under section 1833(t)(2)(E), Congress clearly showed that it would speak expressly where it intends to confer authority to modify payment rates. Thus, it is unreasonable and arbitrary and capricious for CMS to interpret section 1833(t)(2)(F) as permitting a reduction in payment for clinic services furnished by excepted PBDs.

Second, the proposed payment reduction also is arbitrary and capricious because there is no basis for CMS to conclude that OPD services have increased unnecessarily. Agency action is arbitrary and capricious where the agency fails to consider a statutorily mandated factor—in this case, whether increases in volume are “unnecessary.”¹³ **Therefore, even if section 1833(t)(2)(F) could be read to permit a reduction in payment, CMS has no basis to act because the agency did not make the predicate finding.**

¹¹ SSA § 1833(t)(2)(F).

¹² Oxford English Dictionary (definition of “method”).

¹³ See generally *Public Citizen v. Federal Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004) (agencies must consider statutorily mandated factors).

CMS has characterized its proposal as applying section 1833(t)(2)(F), which is an authority that CMS has never previously used to adopt a “method” (or other policy).¹⁴ The agency relies largely on prior Medicare Payment Advisory Commission (MedPAC) recommendations and estimates in saying it believes “increase[s] in the volume of clinic visits is due to the payment incentive that exists to provide this service in [a] higher cost setting.” Furthermore, the agency believes that “the shift of services from the physician office to the hospital outpatient department [is] unnecessary if the beneficiary can safely receive the same services in a lower cost setting.”¹⁵ But the MedPAC data CMS relies on shows only that volume and costs have increased—not that the increased volume is “unnecessary.”¹⁶ **Indeed, CMS mischaracterizes and misquotes a key MedPAC finding, stating that MedPAC reported “A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the *unnecessary* shift of services from (lower cost) physician offices to (higher cost) HOPDs”¹⁷ (emphasis added). In fact, what MedPAC actually said was simply “Another large source of growth in spending on HOPD services appears to have been the shift of services from (lower cost) physician offices to (higher cost) HOPDs.”¹⁸ By inserting the word “unnecessary” where it did not exist in MedPAC’s report, CMS appears to be attempting to meet its statutory burden.** Instead, CMS has irrationally conflated increases in costs with increases in volume, and thereby disregarded the statutory requirement to consider whether the *volume* of outpatient services (as opposed to costs of outpatient services) is increasing unnecessarily.¹⁹

Third, the proposed payment reduction is arbitrary and capricious because the agency failed entirely to consider important aspects of the problem:

- *CMS has failed meaningfully to consider any alternative explanations.* As described further below, CMS attributed increases in outpatient volume to increases in volume at excepted PBDs *without meaningfully considering any alternative explanations* (e.g., shifts from inpatient to outpatient services due to technological advances, changes in beneficiary needs or availability of care on an outpatient basis, the price of drugs, or CMS’s own policy decisions such as the Two-Midnight policy). The proposal fails to recognize the critical role that off-campus PBDs play in their communities in providing convenient access to care for the most vulnerable patients, including the sickest, most medically complex

¹⁴ In 1998, CMS *proposed*, but ultimately did not adopt, a policy that invoked section 1833(t)(2)(F). As discussed below, that policy would not have reduced payments for particular services and would instead have involved the exercise of the agency’s express authority to adjust the conversion factor under what is now section 1833(t)(9)(C). 63 Fed. Reg. 47,552, 47,585 (Sept. 8, 1998) (proposed rule).

¹⁵ 83 Fed. Reg. 37,046, 37,142 (July 31, 2018) (proposed rule).

¹⁶ MedPAC therefore did not say that the services provided in hospital outpatient departments were “unnecessary.” Instead, MedPAC focused on the cost differential relative to if the services had been delivered in a physician office setting. MedPAC, *Report to Congress: Medicare Payment Policy 71* (Mar. 2018).

¹⁷ 83 Fed. Reg. 37,140 (July 31, 2018) (proposed rule).

¹⁸ MedPAC, *Report to Congress: Medicare Payment Policy 73* (Mar. 2018)

¹⁹ *Cf. B&D Land and Livestock Co. v. Schafer*, 587 F.2d 1182, 1199 (N.D. Iowa 2008) (agencies act arbitrarily when they conflate factors that Congress requires them to consider with other factors).

patients. It also fails to recognize that physicians frequently refer Medicare beneficiaries to a HOPD for critical services they do not provide in their offices. Blaming increases in OPPS expenditures on the “unnecessary” shifting of services from physician offices to PBDs ignores factors outside of hospitals’ control that may drive expenditure increases.

- *CMS has ignored evidence that runs contrary to its conclusions.* CMS failed to address the fact that the growth in outpatient services *pre-dates the introduction of the inpatient PPS in 1983*—much less any incentives purportedly created by the current provider-based rules.²⁰
- *CMS has not explained how its proposal will actually solve the policy problem identified by section 1833(t)(2)(F).* CMS has not explained the expected effect of the proposed lower payment rates on OPD utilization—i.e., why the *total volume* of covered OPD services (as opposed to merely how much CMS pays) will *actually go down* in response to CMS’s proposal.²¹

Finally, the proposed payment reduction is arbitrary and capricious because CMS lacks evidence to support its assertion that payment differentials are causing purportedly unnecessary increases in volume. **It is appropriate for CMS to change hospital payment policies only when CMS’s proposals are based on reasonable assumptions and sufficiently precise information to support the agency’s considered reasoning.**²² **The proposed reduction to the CY 2019 clinic visit services payment fails on all counts.**

CMS cannot justify its proposed policy by relying on “conclusory statement[s]” grounded in the agency’s speculation about data it has not even said exists.²³ But the only meaningful support that CMS points to for its conclusions is a March 2018 MedPAC report. In the first place, as noted above, MedPAC was focused on growth in *spending*—not whether the *total volume* of outpatient services is unnecessarily increasing, which is the statutorily required factor to consider under section 1833(t)(2)(F). In any event, MedPAC had sparse evidence to support its conclusions: Without materially considering other possible alternative explanations, MedPAC simply *asserted* that increases in spending “appear[]” attributable to shifts of services from physician offices to HOPDs because HOPD clinic visits were increasing more quickly than physician office clinic visits.²⁴ “This is tantamount to [MedPAC] saying it would ‘not be surprised’ if” volume at hospital outpatient departments increased due to shifts in

²⁰ See, e.g., M. Gold, *The Demand for Hospital Outpatient Services*, 19 Health Serv. Res. 383, 384 (1984) (noting that the demand for outpatient services rapidly expanded in the 1970s and 1980s—and doubled from 1969 to 1984), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1068820/>.

²¹ In other words, it is unclear why CMS’s proposal to pay less for clinic visits furnished by excepted facilities will actually reduce the total volume of outpatient services—as opposed to shifting volume between two different outpatient settings.

²² See 5 U.S.C. § 706(2)(A).

²³ *Allied-Signal v. U.S. Nuclear Regulatory Comm’n*, 988 F.2d 136, 152 (D.C. Cir. 1993).

²⁴ MedPAC, *Report to Congress: Medicare Payment Policy* 73 (Mar. 2018).

volume from physician office settings, “but it is far short of ... substantiating[] that it was ‘likely’ the[]” cause.²⁵

CMS’s reliance on MedPAC’s “unsupported assertion[s] does not amount to substantial evidence,” and is “insufficient to make the agency’s decision non-arbitrary.”²⁶ It is well established under the Administrative Procedure Act (APA) that “[s]peculation is no substitute for evidence.”²⁷ “[A]n agency’s ‘declaration of fact that is capable of exact proof but is unsupported by any evidence’ is insufficient to make the agency’s decision non-arbitrary.”²⁸ The rulemaking record must contain the specific evidence needed to support a rational nexus between specific facts found and an agency’s proposed course of action.²⁹ CMS cannot simply assume that outpatient volume increases are unnecessary because it “suspects” that MedPAC was correct to believe that clinic visits could have been delivered in a different (and cheaper) outpatient setting.³⁰ Rather, CMS needs *actual evidence* to support its conclusions and to show that increases in volume were “unnecessary” and that its proposal will meaningfully reduce the total volume of OPD services.³¹

The Proposed Non-budget Neutral Payment Reduction Is Unlawful. Under CMS’s proposal, the reduction in payments for clinic services furnished by excepted PBDs would not be budget neutral. Like the proposed payment reduction itself, making the reduction in a non-budget neutral manner is unlawful. CMS reasons that it has authority to implement its proposal in a non-budget neutral fashion because, “while section 1833(t)(9)(B) of the Act generally requires that changes made under the OPSS be made in a budget neutral manner ... this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act.”³² According to CMS, the budget neutrality requirement applies to “wage and other adjustments,” not to “methods.”³³

CMS’s interpretation runs afoul of the plain language of the law because section 1833(t)(2)(F) authorizes only that CMS “develop a *method* for controlling unnecessary increases in the volume of covered OPD services.”³⁴ Because CMS lacks authority to reduce clinic visit payment rates under section 1833(t)(2)(F), as explained above, that provision cannot provide authority for the payment reduction to be made in a non-

²⁵ *McDonnell Douglas Corp. v. U.S. Dep’t of the Air Force*, 375 F.3d 1182, 1190 (D.C. Cir. 2004)

²⁶ *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 605 (D.C. Cir. 2007).

²⁷ *White ex rel. Smith v. Apfel*, 167 F.3d 369, 375 (7th Cir. 1999).

²⁸ *Safe Extensions, Inc.*, 509 F.3d at 605.

²⁹ *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1582–83 (10th Cir. 1985) (“[t]here are limits. . . to the degree of imperfection that is permissible” in data that an agency relies on); see also *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561, 1568 (D.C. Cir. 1985).

³⁰ See *McDonnell Douglas Corp.*, 375 F.3d at 1190.

³¹ See, e.g., *Flyers Rights Educ. Fund, Inc. v. Fed. Aviation Admin.*, 864 F.3d 738, 741 (D.C. Cir. 2017) (an agency cannot rely on off-point studies and tests using unknown parameters to justify its conclusions—the “Administrative Procedure Act” requires more than “[t]hat type of vamporous record” and instead “requires reasoned decision-making grounded in *actual evidence*”) (emphasis added).

³² 83 Fed. Reg. 37,046, 37,142.

³³ *Id.*

³⁴ SSA § 1833(t)(2)(F).

budget neutral way.³⁵

Moreover, we know that Congress did not authorize a *non-budget neutral* reduction in payments for clinic visits because Congress expressly detailed what CMS was authorized to do if the agency identified an unnecessary increase in service volume under section 1833(t)(2)(F). Congress said that the only non-budget neutral option available to the agency was to *adjust the update to the conversion factor* in a subsequent year, as expressly provided under section 1833(t)(9)(C).³⁶ Not only is this clear from the plain text of section 1833(t), but it also is clear from the legislative history. In the conference report associated with section 1833(t)'s enactment, Congress explained that CMS "adjustments ... would be made in a budget neutral manner. If the [agency] determined that the volume of services paid for under [section 1833(t) ... increased beyond amounts established through those methodologies, [it] would be authorized to adjust the update to the *conversion factor* otherwise applicable in a subsequent year."³⁷

And this also is how CMS itself historically has interpreted section 1833(t)(2)(F): It has regarded adjustments to conversion factor updates (under section 1833(t)(9)(C)) as the appropriate mechanism for dealing with overutilization.³⁸ There is neither a legal nor a factual basis for CMS to take a different view of its authority now.

In addition, CMS's proposal is completely inconsistent with the structure of section 1833(t). If Congress had intended to confer authority to make *non-budget neutral* payment changes under section 1833(t)(2)(F), there is every reason to think that Congress would say so in clear and express terms as it did elsewhere in section 1833(t). Permitting CMS to make non-budget neutral payment modifications represents a significant grant of authority by Congress. When CMS makes a budget neutral payment reduction for a particular item or service, the reduced payment is offset by increased payments to hospitals for other items or services. All of the payment adjustments expressly authorized by section 1833(t)(2) require budget neutrality. Although individual hospitals may be made better or worse off due to the budget neutral

³⁵ Cf. *Tarbell v. Dep't of Interior*, 307 F. Supp. 2d 409, 429 (N.D.N.Y. 2004) (an agency fails to engage in the type of "meaningful analysis" required by the APA if its conclusions are premised on a mistaken interpretation of what the law requires); *Petties v. D.C.*, 298 F. Supp. 2d 60, 66 (D.D.C. 2003) (if an agency policy is unlawful, "[i]t follows that" the agency "cannot rely" on the policy as the justification for subsequent action taken by the agency).

³⁶ CMS's proposal is therefore not only an unreasonable interpretation of the statute but also clearly exceeds the authority delegated to the agency by Congress. See *Univ. of D.C. Faculty Ass'n /NEA v. D.C. Fin. Responsibility & Mgmt. Assistance Auth.*, 163 F.3d 616, 620 (D.C. Cir. 1998) (an agency action is *ultra vires* when the legislative text and other statutory materials show that "Congress [did not] intend[] the . . . [agency] to have the power that it exercised when it [acted].").

³⁷ Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.) (emphasis added).

³⁸ See 72 Fed. Reg. 66,580, 66,613, 66,621 (Nov. 27, 2007) (CMS noting that "[s]ection 1833(t)(2)(F) of the Act requires [it] to develop a method of controlling unnecessary increases in the volume of covered OPS services" and going on to explain that "section 1833(t)(9)(C) of the Act authorizes [it] to *adjust the update to the conversion factor* if under section 1833(t)(2)(F) of the Act, [CMS] determine[s] that there is growth in volume that exceeds established tolerances.") (emphasis added); 63 Fed. Reg. 47,552, 47,585 (Sept. 8, 1998) (CMS explaining that if "the volume of services paid for increases beyond amounts established through methodologies determined in section 1833(t)(2)(F)," then "section 1833(t)(9)(C) . . . [allows CMS to adjust the] update to the conversion factor.").

reduction, *hospitals as a whole* will receive the same amount of payment from Medicare when a payment reduction is implemented on a budget neutral basis. This design reduces the incentive for CMS to make draconian payment reductions targeting specific services.

By contrast, a non-budget neutral payment reduction reduces the *total* amount that Medicare pays across all hospitals. The authority to implement a non-budget neutral payment reduction is therefore materially more significant than budget neutral payment adjustment authority.

Given the importance of budget neutrality as a check on CMS's discretion, Congress would not authorize non-budget neutral payment modifications through vague language like the ambiguous reference to developing a "method" found in section 1833(t)(2)(F).

First, "Congress ... does not alter [] fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."³⁹

Second, we know that Congress would speak expressly when it intends to authorize non-budget neutral payment changes because *that is what Congress has done* elsewhere in section 1833(t).⁴⁰ For example, section 1833(t)(7)(I) expressly authorizes certain payments to be made in a "not ... budget neutral" manner.⁴¹ "[W]here Congress knows how to say something but chooses not to, its silence is controlling."⁴² It is clear from the structure of section 1833(t) that if Congress had wanted section 1833(t)(2)(F) to incorporate authority to make non-budget neutral payment changes, Congress would have said so expressly.

Finally, CMS's proposal to make a reduction in payment for clinic visits in a non-budget neutral manner is arbitrary and capricious for the same reasons that the underlying payment reductions would be arbitrary and capricious. As discussed in more detail above, CMS has failed to consider an important aspect of the problem and also failed to provide sufficient evidence to support its assertion that outpatient volume has increased "unnecessarily." CMS has not provided sufficient evidence or rationale to justify its proposed payment reductions—much less to make those reductions in a non-budget neutral fashion.

³⁹ *American Trucking Ass'n*, 531 U.S. at 468.

⁴⁰ Cf. Letter from Marilyn Tavenner, Administrator, CMS, to Daniel R. Levinson, Inspector General, Office of the Inspector General (OIG) at 2 (Dec. 13, 2013) (rejecting an OIG recommendation that CMS reduce OPPS rates in a non-budget neutral fashion for certain low-risk services to ambulatory surgical center payment levels because, among other things, "adopting the[] recommendation[] would require legislation"), available at <https://oig.hhs.gov/oas/reports/region5/51200020.pdf>.

⁴¹ Further underscoring that it intended to be very clear when it was authorizing budget neutral versus non-budget neutral modifications, Congress *also* spoke expressly when authorizing budget neutral payment reductions. For example, section 1833(t)(2)(E) requires CMS to establish, in a budget neutral fashion, (1) an outlier payment "adjustment," (2) a transitional pass-through, and (3) such "other adjustments" as are necessary to ensure equitable payments.

⁴² *Lindley v. FDIC*, 733 F.3d 1043, 1056 (11th Cir. 2013), *aff'd sub nom. Lokey v. FDIC*, 608 F. App'x 736 (11th Cir. 2015).

The Growth in Outpatient Volume and Expenditures is not “Unnecessary”. CMS proposes to impose this 60 percent cut in payment for a clinic visit, an essential hospital outpatient service, without presenting any of its own data analysis on:

- Clinic visit volume;
- Clinic visit expenditures;
- The “unnecessary” nature of clinic visit volume or expenditures;
- The “shifting” volume of clinic visits from physician offices to excepted off-campus PBDs due to payment differentials; or
- How a reduction in payment for the hospital outpatient clinic visit is a “method” that would lead to a reduction in the volume of “unnecessary” services in excepted off-campus PBDs.

Indeed, this complete lack of data, analysis and evidence did not go unnoticed. **At the Aug. 20 meeting of CMS’s Advisory Committee on Hospital Outpatient Payments, the panel unanimously recommended that CMS *not implement* the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions. Instead, the Panel recommended that CMS study the matter to better understand the reasons for increased utilization of outpatient services, since it clearly had not done so in the proposed rule.**

Panel members further noted that the outpatient clinic visit is a valuable service that is necessary for treating Medicare beneficiaries who have co-morbid conditions, avoiding ED visits, and minimizing inpatient readmissions. CMS itself has encouraged and incentivized models of care that rely on these outpatient hospital visits to bridge patients from inpatient discharge to the time they can see their primary care or specialists in the office settings. More beneficiaries have the co-morbid conditions that require these services and offices are not equipped with the specially trained nurses, technologists, and pharmacists who render these services.

Blaming increases in OPSS expenditures on the “unnecessary” shifting of services from physician offices to PBDs, in response to payment differentials, ignores all the many factors outside of hospitals’ control that also result in increases in OPSS volume and expenditures. This includes such things as changes in patient demographics and clinical needs, technological advances, changing economic incentives from CMS and other payers, the impact of other Medicare policies that are either intended to increase the volume of services in PBDs, drug price inflation, or the fact that physicians often refer Medicare beneficiaries to HOPDs for services they do not provide in their offices.

We describe below some of the many factors that may be contributing to increases in OPSS volume.

Medicare Policies that Shift Care to PBDs. Medicare has many policies that are intended to promote greater use of outpatient services or that otherwise incentivize

increases in outpatient services, a few of which are outlined below. By definition, increases in volume and expenditures in PBDs that result from these policies cannot be seen to be “unnecessary”. Yet, CMS did nothing to analyze the effect of these policies.

- **Readmissions Program.** The Hospital Readmission Reduction Program penalizes hospitals up to three percent of their Medicare inpatient prospective payment system (PPS) payments for having excessively high rates of readmissions. To reduce readmissions, many hospitals have focused on carefully coordinating post-hospitalization care. For example, hospitals encourage patients to keep follow up appointments, use outpatient rehabilitative services and consult their clinician offices if they experience sub-acute level complications with their care. The result is that while these strategies result in better care and reduce the need for hospitalization, they also can lead to greater use of outpatient services. These increases in outpatient volume are an entirely appropriate and intended effect of this program.
- **Value-based Care.** Hospitals have been deeply involved in redesigning the health care system and improving quality for Medicare beneficiaries while maintaining or lowering costs. Many of these efforts, such as the accountable care organization (ACO) program, involve creating integrated delivery networks through which hospitals can shift care to lower-acuity settings – including to the outpatient setting. The success of the ACO program, which saved Medicare \$314 million in 2017, is therefore yet another exogenous, but appropriate, driver of the increase in outpatient spending cited by CMS.
- **Two-Midnight Policy.** In FY 2014, CMS implemented its “two-midnight” policy, under which hospital inpatient admissions spanning at least two midnights are generally considered as reasonable and necessary for payment under Part A. An [AHA analysis](#) has demonstrated that this policy resulted in a net shift of care from the inpatient to outpatient setting. Specifically, after explicitly accounting for and recognizing that inpatient stays were decreasing even prior to implementation of the two-midnight policy, our analysis showed that in FY 2014 alone, the two-midnight policy resulted in a net shift of almost 200,000 inpatient stays to the outpatient setting. MedPAC, too, has recognized this trend, stating that “[s]ome of the growth in the...HOPD setting is from a shift of services from the inpatient setting to the outpatient setting,” and specifically cites “the introduction in [FY] 2014 of a two-midnight rule for inpatient stays” as a reason.⁴³ Thus, CMS’s own two-midnight policy is driving increases in outpatient volume and expenditures.
- **Packaging of Clinical Laboratory Services into the OPSS.** In CY 2014, CMS packaged most clinical laboratory tests into the OPSS payment rates. Previously these tests had been paid under the clinical laboratory fee schedule (CLFS). CMS initially estimated that change amounted to an additional \$2.4 billion bundled into the OPSS. This shift of costs from the CLFS to the OPSS explains, in part, the unusually

⁴³ MedPAC Report to the Congress: Medicare Payment Policy, March 2018.

large increase in OPSS spending from 2013 to 2014 (a 12.8 percent increase).⁴⁴ Yet once again, CMS does nothing to discuss how its own policy increases OPSS expenditures.

- Changes to the Inpatient Only (IPO) List. Each year CMS reviews the current list of procedures on the IPO list to identify any procedures that may be safely removed from the IPO list and payable under Medicare when performed in PBDs. Over the last five years, the agency has removed 24 procedures from this list, including, notably, total knee arthroplasty. The shifting of Medicare procedures from the inpatient to the outpatient setting is an intended and entirely appropriate result of this policy and is another driver of OPSS volume and expenditures.

Factors Outside of the Hospitals Control that Increase OPSS Volume and Expenditures. There are many broader health care trends that contribute to the increase in OPSS expenditures, all of which are outside of the hospitals' control. We highlight a few below. Again, by definition, increases in volume and expenditures resulting from these trends cannot be considered "unnecessary", although CMS did not even attempt to analyze their effect either.

- Drug Price Inflation. Table 30 in the proposed rule, which describes the growth in expenditures under OPSS from CY 2010 through 2019, is used by CMS to justify its proposed policy intended to address "unnecessary" growth in volume in the OPSS. However, a footnote in the table indicates that the growth rates shown include Medicare Part B drug expenditures. Drug price inflation is a key factor contributing to the growth in OPSS expenditures that is entirely outside of the control of hospitals. Indeed HHS, MedPAC, and others have expressed concern about the rapid growth in drug expenditures. According to MedPAC "Since 2009, Medicare Part B drug spending grew at an average rate of about 9 percent per year. About half of that growth in Part B drug spending between 2009 and 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs."⁴⁵

However, in more recent years, drug price increases have skyrocketed even more to become the major factor in increases in Part B drug expenditures. **Based on an AHA analysis of Medicare data, from 2015 through 2016, Medicare spending on all Medicare Part B separately payable drugs increased more than seven percent. About 96 percent of that growth was due to increases in drug prices – not utilization.**

During the same time period, spending on outpatient separately payable drugs grew by approximately 11 percent. However, the prices of outpatient separately payable drugs grew at an even higher rate of about 11.28 percent; thus, over 100 percent of

⁴⁴ MedPAC Report to the Congress: Medicare and the Health Care Delivery System, June 2017.

⁴⁵ MedPAC Report to the Congress: Medicare Payment Policy, March 2018.

the growth during this time was attributable to price increases of outpatient, separately payable drugs. The utilization of these drugs *decreased* over the same period of time. **This increase represents about \$1 billion in additional spending compared to if no average sales price (ASP) changes had occurred. Thus, over one-quarter of the \$3.6 billion increase in OPPS expenditures from 2015 to 2016 can be explained by increased Part B drug prices.**

- Physician Referrals. Some of the increase in outpatient expenditures under the OPPS is the result of independently practicing physicians referring beneficiaries to the PBD for services that the physician does not deliver in his or her office, such as wound care or Coumadin clinic services. These types of referrals are clearly not the result of an “unnecessary” shifting of services from a lower cost to a higher cost setting because the services rendered by the PBD are not available in physician offices.

Making Cuts to Hospital Reimbursements of the Magnitude Proposed in the Clinic Visit Policy Would Be Excessive and Harmful. As noted above, CMS proposes to pay for clinic visits furnished in excepted off-campus PBDs at the “PFS-equivalent” rate of 40 percent of the OPPS rate. This policy would be implemented in a non budget-neutral manner, which the agency estimates would result in a CY 2019 reduction of \$760 million in hospital payment under the OPPS. **Making additional cuts to outpatient payment of the magnitude proposed in the clinic visit policy would be excessive and harmful. It would endanger the critical role that hospital outpatient departments (HOPDs) play in their communities, including providing convenient access to care for the most vulnerable beneficiaries, including the sickest, most medically complex patients.**

Specifically, among all Medicare beneficiaries, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and EDs;
- Are more likely to live in low-income areas;
- Are 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.4 times more likely to be non-white;
- Are 1.6 times more likely to be under age 65 and disabled; and
- Are 1.1 times more likely to be over 85 years old.⁴⁶

Among Medicare beneficiaries with cancer, the differences in the types of patients seen in HOPDs compared to physician offices is even more stark. That is, relative to cancer patients seen in physician offices, cancer patients seen in HOPDs not only have more severe chronic conditions, higher prior utilization of

⁴⁶ Source: Analysis prepared for the AHA by KNG Health Consulting Inc., “Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices, June 29, 2018.

hospitals and EDs, and higher likelihood of residing in low-income areas, but also:

- Are 2.3 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.9 times more likely to be non-white; and
- Are 2.4 times more likely to be under age 65 and disabled.⁴⁷

According to the FY 2016 Medicare cost report data, Medicare margins for outpatient services were a record low of negative 14.8 percent in 2016.⁴⁸ Overall Medicare margins were a record low of negative 9.6 percent in 2016, with a new record low of negative 11.0 percent projected for 2018.⁴⁹ Of note, for the first time ever, even “efficient” hospitals had a negative margin in 2016.⁵⁰ **The site-neutral payment policies implemented by CMS for 2017 and beyond will reduce these margins further.** We are concerned that this, in turn, would threaten beneficiary access to critical hospital-based “safety-net” services and would undermine the ability of hospitals to adequately fund their 24/7 emergency standby capacity. **For better or worse, the hospital safety-net and emergency stand-by role are funded through the provision of all outpatient services. If CMS continues to erode this funding, so too will these critical services be eroded.**

And, as spurred by the steady decline in Medicare margins over the past two decades, this is exactly what we have seen. As documented by the North Carolina Rural Health Research Program, 87 rural hospitals have closed since 2010, 57 of them since just 2014.⁵¹ While MedPAC and others dismiss these closures by noting that the hospitals were “small” or “near other facilities,” the concern remains that these very vulnerable rural hospitals are the “canaries in the coal mine.” **They serve as the initial indicators that we are beginning to reach a tipping point where private payers are no longer willing to fund, and hospitals can no longer sustain, operations on the cost-shift that such considerable Medicare underpayments, particularly those under OPPS, necessitate.**

Site-neutral Policies are Based on Flawed Assumptions. Finally, the entire premise of CMS’s site-neutral policies are based on the flawed assumption that Medicare PFS payment rates are sustainable rates for physicians. However, the truth is much different. AHA members tell us is that when they acquire independent physician practices, it occurs because the physicians have reached a tipping point – their practices are failing due to poor payer mix, increasing Medicare and Medicaid regulatory burden, and declines in Medicare and Medicaid reimbursement. Instead of allowing these physician services to be lost to the community, or in communities where there are already health

⁴⁷ Source: Analysis prepared for the AHA by KNG Health Consulting Inc., “Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices among Cancer Patients, June 29, 2018.

⁴⁸ Source: AHA analysis of FY 2016 Medicare cost reports.

⁴⁹ MedPAC’s March 2018 Report to the Congress: Medicare Payment Policy.

⁵⁰ MedPAC’s March 2018 Report to the Congress: Medicare Payment Policy.

⁵¹ <http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>, accessed on Sept. 11, 2018.

care deserts, hospitals purchase the practices in order to ensure continued access to these services.

All of this supports the conclusion that CMS’s own HOP Panel came to — that CMS should withdraw its proposed policy to drastically reduce payment for outpatient clinic visits in excepted PBDs.

PROPOSED POLICY ON EXPANSION OF CLINICAL FAMILIES OF SERVICES AT EXCEPTED OFF-CAMPUS PBDs

When CMS first implemented section 603 in CY 2017, the agency proposed to limit the services for which payment would be made under the OPSS in an excepted off-campus PBD to those services furnished before Nov. 2, 2015. It proposed to pay for other services that were not included as part of a clinical family of services furnished by the excepted off-campus PBD before that date as nonexcepted services subject to payment under the PFS. However, comments from stakeholders expressed concerns about the proposal, including that CMS lacked the authority to implement the policy, that limiting service expansion would stifle innovative care delivery and new technologies, and that the proposal was not workable. As a result, the agency did not finalize this proposal but indicated it would continue to monitor service line expansion and consider how potential limitations on expansion might work by inviting stakeholder comments.

In the CY 2019 proposed rule, CMS again expresses concern that allowing expansion of services in excepted off-campus PBDs incentivizes hospitals to purchase additional physician practices and add those physicians to an existing excepted off-campus PBD, in a manner that the agency believes is inconsistent with the intent of section 603. As such, CMS proposes to revise the definition of “excepted items and services” to apply only to those services from clinical families of services from which the excepted off-campus PBD furnished a service (and subsequently billed for that item or service under the OPSS) during certain baseline periods (generally from Nov. 1, 2014 through Nov. 1, 2015). CMS proposes 19 families of service for use in making this determination.

To comply with this proposed policy, CMS would require excepted off-campus PBDs to ascertain the clinical families of services from which they furnished services during the baseline period. Any items and services furnished by the excepted off-campus PBD after the baseline period, that are not among the families of service furnished and billed under the OPSS during the baseline period, would no longer be excepted services. Instead, starting Jan. 1, 2019, such services would be required to be reported with modifier “PN,” indicating nonexcepted services paid under the PFS. CMS also notes that items and services not identified among the 19 families of services included in the proposed rule that are furnished by excepted off-campus PBDs would also be nonexcepted services paid under the PFS.

The AHA strongly opposes the families of service expansion proposal and urges the agency to withdraw it. We are disappointed that CMS has resurrected this flawed and entirely unsupported proposal, which it had previously, and appropriately, rejected. In short:

- **The proposal is arbitrary and capricious. CMS lacks statutory authority to pay new clinical families of service in excepted off-campus PBDs at the rate paid to nonexcepted PBDs.**
- **The proposal would hamper innovation and reduce beneficiary access to care. Preventing excepted off-campus PBDs from being able to expand in order to meet the changing needs of their communities would be tantamount to freezing them in time, usurping their ability to keep up with the evolution of evidence-based medicine.**
- **Compliance with the proposal would pose nearly insurmountable operational challenges and regulatory burden on hospitals, contrary to the agency's stated goals.**
- **CMS's proposal would raise many operational issues and questions that are not addressed in the proposed rule.**

Paying Excepted Off-campus PBDs at the Rates Paid to Nonexcepted PBDs for New Families of Services Would Be Unlawful. CMS lacks statutory authority to pay new clinical families of services furnished by excepted off-campus PBDs at the rate paid to nonexcepted PBDs. In addition, paying less for new clinical families of services would be arbitrary and capricious.

First, in its proposal to pay excepted off-campus PBDs at the rate of nonexcepted PBDs for new families of services, CMS itself does not clearly explain the basis of its statutory authority. CMS asserts that the policy is grounded in the amendments to section 1833(t) added by section 603,⁵² but does not point to any specific sub-provision of section 1833(t). Nor could CMS plausibly do so: none of the sub-provisions added by section 603 could serve as a statutory basis for the proposal.

As noted above, section 603 establishes two classes of off-campus PBDs: (1) excepted off-campus PBDs, which were billing under OPPS for OPD services prior to the enactment of section 603 and which continue to be paid under the OPPS system, and (2) nonexcepted off-campus PBDs, which are paid under an applicable payment system other than OPPS and designated by CMS.⁵³ Under section 1833(t)(21)(B)(ii), excepted off-campus PBDs continue to be paid under OPPS because they were "billing under [OPPS] with respect to covered OPD services furnished prior to the date of the

⁵² 83 Fed. Reg. 37,046, 37,147–49.

⁵³ As explained elsewhere in this document, CMS has not actually implemented this statutory requirement. CMS instead pays nonexcepted off-campus PBDs under the OPPS system but applies a PFS Relativity Adjustor, which CMS says is intended to approximate payment under the applicable payment system (which CMS has designated to be the PFS).

enactment of” section 603,⁵⁴ and nothing in this statutory regime authorizes CMS to take excepted off-campus PBDs out of OPSS with respect to “certain” families of covered OPD services.

The only authority that CMS has under section 1833(t)(21) is to alter the applicable payment system for off-campus PBDs that were *not* billing under OPSS with respect to covered OPD services prior to the enactment of section 603. The statutory authority is binary. The statute does not give CMS authority to try to blur the lines between excepted and nonexcepted PBDs, and thereby disregard a clear and categorical delineation drawn by Congress through its enactment of section 1833(t)(21). Doing so would be *ultra vires*. It also would be arbitrary and capricious.

First, it would be unlawful for CMS to treat facilities as excepted *solely* for purposes of services for which they would have been excepted at the date of enactment of section 603. This would be inconsistent with the text of section 1833(t)(21). CMS would effectively be reading the exception to apply “with respect to OPD services billed by an off-campus PBD prior to the enactment of section 603.” But this is *not* what the exception actually says: The exception applies if the *off-campus PBD* was “billing under [OPSS] ... with respect to covered OPD services” before the enactment of section 603. In other words, the statutory language makes it irrelevant whether any particular group of covered OPD services was billed prior to the enactment of section 603 (so long as *some* covered OPD services were billed under OPSS).

Second, there is no support in the legislative history for CMS’s proposal. CMS itself does not point to any supporting legislative history for its assertion that its proposal implements section 603.⁵⁵ CMS instead says that “there is no congressional record available for section 603” but the agency nonetheless “does not believe Congress intended to allow for new service lines to be paid OPSS rates.”⁵⁶ “It is one thing to construe a section of a comprehensive statute in the context of its general scheme, as that scheme is indicated by its terms and by the gloss of those authorized to speak for Congress, either through reports or statements on the floor. It is a very different thing to extrapolate meaning from surmises and speculation....”⁵⁷

CMS cannot manufacture congressional intent (much less a valid basis of statutory authority for its unlawful action) from the complete absence of a legislative record. This is particularly true here, where the plain statutory text (which is the strongest evidence of Congress’s actual intent)⁵⁸ unambiguously demonstrates that Congress intended to except *entire facilities*, so long as those facilities were billing OPSS prior to Nov. 2,

⁵⁴ *Id.* § 1833(t)(21)(B)(ii).

⁵⁵ CMS does cite to various materials that are *not* legislative history (or statutory language) in justifying its proposal. See *id.* at 37,147–48 (citing a non-contemporaneous and seemingly misdated letter from the Committee on Energy and Commerce and a GAO report).

⁵⁶ *Id.* at 37,148.

⁵⁷ *United States v. Pub. Utilities Comm'n of Cal.*, 345 U.S. 295, 321 (1953) (Frankfurter, J., *dubitante*).

⁵⁸ See, e.g., *Resolution Tr. Corp. v. O'Bear, Overholser, Smith & Huffer*, 840 F. Supp. 1270, 1277 (N.D. Ind. 1993) (“The plain language of a statute is the strongest evidence of congressional intent.”).

2015.⁵⁹ As a majority of both Houses of Congress previously explained to CMS in May of 2016, “[t]he *only* criteri[on] under [s]ection 603 for being designated as an existing HOPD rather than a ‘new’ HOPD is that the facility was billing under the OPSS prior to Nov. 2, 2015.”⁶⁰

CMS’s speculation about Congress’s intent is therefore insufficient to serve as a valid statutory basis for its proposal. Further, the agency’s reliance on such speculation renders CMS’s proposal arbitrary and capricious. It is arbitrary and unreasonable for CMS simultaneously to acknowledge there is no legislative history for section 603 and then to seek to justify its proposal based on Congress’s intent. CMS has also failed rationally to explain how it can infer congressional intent, when the agency itself acknowledges there is *no legislative history* and the agency’s interpretation is completely unmoored from the plain text of section 603.

Third, there similarly is no statutory basis for dividing up items and services by “clinical family,” and doing so would be arbitrary and capricious. Nothing in section 603 provides CMS authority to divvy up categories of covered outpatient services and then reimburse an excepted provider-based PBD as if it were nonexcepted for certain categories of services. Rather, as discussed, if a facility was “billing ... [OPSS] with respect to covered OPD services prior to” November 2, 2015, the facility is *categorically excepted* from the payment system changes enacted by section 603.

Fourth, there also is no statutory basis for CMS’s baseline period. CMS proposes that there be a baseline period from November 1, 2014 to Nov. 1, 2015—and that only services furnished by excepted off-campus PBDs during that baseline period be grandfathered. Even assuming CMS can partially grandfather a facility, which it cannot, this baseline period is contrary to the statute. A facility (or “partial” facility) can be grandfathered so long as it was billing *any time* prior to the enactment of section 603 on Nov. 1, 2015 (not merely from Nov. 1, 2014 to Nov. 1, 2015). CMS’s proposal to use a one-year period is simply arbitrary.

Finally, CMS cannot legally abrogate the statutory mid-build exception: The mid-build exception applies when an off-campus PBD was mid-build before Nov. 2, 2015 and satisfies certain attestation and enrollment requirements. CMS proposes that for such mid-build facilities, the agency apply a 1-year baseline period from the date the off-campus PBD first furnished a service under OPSS. There is no basis in the statutory language for applying a restrictive baseline period. Rather, like the section 603 exception, facilities are either excepted or nonexcepted. The statute does not contemplate “partially” excepted off-campus PBDs, regardless of whether the facility was excepted under section 603 or the 21st Century Cures Act’s mid-build exception.

⁵⁹ See SSA § 1833(t)(21)(B)(ii) (categorically exempting all off-campus PBDs that were “billing under . . . [OPSS] with respect to covered OPD services furnished prior to the date of the enactment of” section 603).

⁶⁰ Letter to Andrew M. Slavitt, Acting Administrator, CMS, from 235 members of the House of Representatives and 51 Senators (May 24, 2016) (emphasis added).

CMS's Proposed Expanded Families of Service Policy Would Hamper Innovation and Reduce Beneficiary Access to Care. **Excepted off-campus PBDs must be able to expand the types of items and services that they offer in order to be responsive to the changing needs of their communities as well as provide patients with the benefits of advances in clinical practice without suffering the penalty of losing payment under the OPSS.** Given the rapid pace of technological advances in medicine, the treatments and services offered by PBDs today will inevitably evolve to include newer, innovative, and more effective care. However, CMS's policy would unfairly penalize excepted PBDs that expand or diversify the critical services they offer to meet the changing needs of their patients and, as a result, hamper access to innovative technologies and services. **If finalized, this would be tantamount to freezing these excepted off-campus PBDs in time, ruling out their ability to keep up with the evolution of evidence-based medicine. Such a policy simply fails to recognize how medical care continues to change, and it creates a very real possibility that innovation would be stifled and beneficiary access to care reduced.**

This policy would be particularly harmful to beneficiary access in rural areas and other communities where the independent physician practices in the community have reached a tipping point and are failing due to poor payer mix. It would also be very detrimental to beneficiaries in health care "deserts" where certain services are no longer available because they were not financially sustainable due to underpayment from the Medicare PFS and Medicaid.

For example, a hospital located in the upper northwest recently began a \$15 million expansion to its excepted off-campus PBD located in a small town 16 miles away from the main hospital. This expansion is intended to better meet the needs of this underserved community by adding primary care, oncology, and surgery/endoscopy services. It is necessary because almost all of the free-standing physician practices in this town were losing money and have either shut-down or have asked to become employees of the hospital. Indeed, the only free-standing physician practice left is a "concierge" primary care practice that requires payment of a monthly fee that is beyond the means of many of the community's low income seniors. The hospital's CEO reports that despite experiencing a \$2.5 million shortfall last year due to its 97 percent reliance on Medicare and Medicaid – programs which pay at far less than the hospital's costs – the hospital has continued to move forward with the expansion at the off-campus PBD because it is committed to the needs of this community, including local access to primary and specialty care. However, the prospect of a 60 percent reduction in payment for the expanded services furnished in this currently excepted off-campus PBD, as well as the proposed cut for the outpatient clinic visit cut, poses an existential threat to this excepted PBD. If these policies are finalized, the CEO reports that closure of the PBD or a drastic reduction in the scope of services it offers are a likely outcome.

We have heard from many hospitals and health systems who are in similar predicaments, having already expanded services or having expansions in the works that

are intended to offer patients greater access to high-quality, fully integrated care in locations that are closer to their growing populations. They now face the impossible choice of rethinking their plans or considering how they could possibly survive if CMS finalizes its restrictive policy on expansion of services.

The Proposed Clinical Families Expansion Policy Would Impose Insurmountable Operational and Regulatory Burden. **Compliance with the proposed expansion of clinical families policy would pose nearly insurmountable operational challenges and regulatory burden on hospitals, contrary to the agency's stated goals.**

Specifically, to comply with this proposed policy, CMS would require excepted off-campus PBDs to ascertain the clinical families of services from which they furnished services during the baseline period. Hospitals would have only two months to do so, from early November when the final rule is issued, until Jan. 1, when the policy would become effective. This is a wholly inadequate amount of time to accomplish this complex task. In fact, the timeline for compliance would probably be far less than two months because the agency would likely have to issue subregulatory guidance to clarify the details of what it expects and to answer hospitals questions, as noted above.

Further, in order to conduct this analysis, every hospital with one or more excepted off-campus PBDs would have to retrieve claims data from three to four years ago and, for each claim during the baseline period, determine exactly in which location each covered service was furnished (including claims that contain multiple services furnished in multiple locations). Then, separately for each location that is an off-campus PBD, the hospital would have to sort these services into their designated ambulatory payment classifications (APCs) and then into their clinical families. This exercise would require hospitals to crosswalk certain services that may have had changes in their Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology (CPT) codes, and APC assignments since the baseline period.

Once the hospital determines exactly which services, APCs, and clinical families its off-campus PBDs furnished during the baseline period, it would then have to create, test, and launch a process by which it would be able to correctly apply the PO or PN modifier to each service it will furnish in each of its excepted off-campus PBDs starting on Jan. 1, 2019. Since different excepted PBDs will have furnished different services during the baseline period, this process would have to be customized for each excepted off-campus PBD.

Further, the provider-based regulations at 42 CFR 413.65 require that off-campus PBDs must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential copayment liability as a result of their encounter. Because a single patient encounter at an excepted off-campus HOPD could involve some services that are excepted as well as other services that are nonexcepted, calculating beneficiary financial liability will be burdensome.

In an administration that has set as a central objective reducing regulatory burden in health care, this policy runs contrary to its goals, is inappropriate, and should be withdrawn.

CMS Does Not Adequately Consider Operational Issues Regarding the Use of Clinical Families. **CMS's proposed policy for handling expansion of services in excepted PBDs would raise many operational issues and questions that are not addressed in the proposed rule.** As described above, the agency proposes that any expansion of services beyond the clinical families of services that had been furnished by an excepted HOPD during a defined baseline period would no longer be excepted. Service types would be defined by 19 clinical families of hospital outpatient services, composed of groups APCs, as listed in the proposed rule. As such, the agency proposes that if an excepted off-campus HOPD furnishes any specific service within a new clinical family of services that it had not furnished and billed for during the baseline period, that service would be nonexcepted and ineligible to receive payment under the OPFS.

First, the use of APCs to define clinical families raises questions related to how CMS would manage this policy as APCs are refined and replaced over time. Each year, CMS changes the composition and definition of APCs and the CPT/ HCPCS codes contained in those APCs. Therefore, the individual services contained within a clinical family, as defined by the groupings of APCs displayed in the proposed rule for 2019 would change. CMS fails to consider how providers will track such changes, nor does the agency describe how it would treat changes in the component HCPCS/CPT codes and in the APCs themselves as it relates to payment for items and services offered in excepted PBDs.

Second, the impact of changes made over time in the CPT and HCPCS codes also raise complex issues that CMS must address. For instance, the American Medical Association (AMA), which controls the CPT codes, makes changes to existing codes twice a year (as in the case of category III codes). Such changes include revisions of existing codes, deletion of codes and creation of new codes as services change over time. This sometimes leads to services being placed in different sections of the CPT Manual due to a change in the nature of the service. By necessity, this will lead to changes in the assignment of CPT codes to APCs, with the potential for individual CPT codes moving between different clinical families as services evolve. This raises a question about how such services should be treated in an excepted PBD. CMS does not consider whether a service that was furnished during the baseline period would still be excepted if, due to changes in its classification under CPT, it is later assigned to another APC in a different clinical family that was not furnished by the excepted PBD during the baseline period.

Third, the AHA notes that there are several categories of OPFS-covered HCPCS/CPT codes that CMS has neglected to assign a clinical family. These include new technology APCs, partial hospitalization, drugs, dialysis, brachytherapy, and radiotherapy. It is unclear whether this is an oversight or error in the proposed rule or if the agency has

some other unstated intention regarding these services. While some of these services, such as drugs, are not subject to the site-neutral payment policy, CMS should address what these missing APCs mean in the context of the proposed policy. In the proposed rule, CMS states, “In addition, items and services furnished by an excepted off-campus PBD that are not identified below in Table 32 of this proposed rule must be reported with modifier ‘PN’.” For instance, CMS fails to describe whether this policy applies to partial hospitalization APCs, which would mean that all partial hospitalization services furnished in an excepted off-campus PBD would become nonexcepted services, billing with a PN modifier starting in CY 2019.

CMS also fails to explain the significance of the absence of the new technology APCs in the clinical families. This raises several options and their related questions, such as:

- Would all new technology services be required to be billed with a PN modifier, consistent with the policy CMS described in the proposed rule?
- If new technology services would remain excepted under the families of services policy, what would happen when a service assigned to a new technology APC is subsequently assigned to a clinical APC? For instance, would a service assigned to a new technology APC that was furnished during the baseline period at an excepted off-campus PBD suddenly be considered “new” when it is assigned to a clinical APC and therefore deemed to be nonexcepted?
- Would all new technology services be permanently exempted from the clinical families policy, including when they are assigned to clinical APCs?

In addition, CMS does not describe how conditionally packaged services and services that roll up to comprehensive APCs (C-APCs) would be treated under the clinical families policy. For example, if on Jan. 1, an excepted PBD furnishes a service that falls within a clinical family that it had billed during the baseline period, but it is reported on the same claim with a J1 status indicator service (triggering a C-APC payment under which all covered Part B services on the claim are packaged with the primary J1 service for the claim) that was not billed by the excepted PBD during the baseline period, would the resulting C-APC service be paid at the excepted or nonexcepted rate?

The AHA is also concerned that about 43 percent of the 4,614 HCPCS codes contained within the clinical family APCs have an “NA” in the non-facility NA indicator field of the PFS payment table. This means that physicians do not perform the service in an office- (i.e. non-facility) setting. CMS’s rationale for proposing the clinical families policy is that “hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe the section 603 amendments to section 1833(t) of the Act are intended to prevent.” However, these “NA” services are never furnished in physician offices making CMS’s rationale not applicable. Since these services are not expected to be performed in physician offices, when hospitals expand to provide these “NA” services at excepted,

off-campus locations, it is without doubt in response to patient need, not to the purchase of physician practices that had been performing the service.

EXPANSION OF THE ALTERNATIVE PAYMENT METHODOLOGY FOR DRUGS PURCHASED UNDER THE 340B DRUG PRICING PROGRAM

CMS continues its relentless attack on the 340B program in the CY 2019 OPSS proposed rule. Punitively targeting 340B hospitals serving vulnerable communities does not address the basic driver increasing spending on drugs – the skyrocketing cost of pharmaceuticals. **The agency continues to base its current and proposed 340B Medicare payment policies on flawed arguments. The AHA urges CMS to both reverse its current policy and also withdraw its proposed policy. In short:**

- **CMS lacks statutory authority to impose a payment rate for 340B drugs that so dramatically reduces payments and effectively eviscerates the benefits and intent of the 340B program for hospitals.**
- **CMS does not have the legal authority to expand 340B Medicare-related cuts to nonexcepted off-campus PBDs in 340B-participating hospitals because section 603 does not authorize CMS to pay at a rate that is less than the rate paid under the selected “applicable payment system,” namely the PFS, for services, including for Part B drugs.**
- **CMS did not conduct an impact analysis in the CY 2019 OPSS/ASC proposed rule to ensure that the adjustment to the OPSS conversion factor it made in CY 2018 was correct.**

Continuation of 340B Payment Policy. In the proposed rule, the agency perpetuates its misguided policy established in the CY 2018 OPSS final rule, which pays separately payable, non-pass-through drugs, acquired through the 340B program at the rate of the ASP minus 22.5 percent.⁶¹ The AHA’s strong opposition to CMS’s policy remains undaunted as demonstrated by our most recent court case challenging the rule, filed in federal court on Sept. 5.⁶² In this litigation, we have demonstrated that the agency lacks statutory authority to impose such a drastic reduction in the payment rate for 340B drugs, effectively eviscerating the benefits of the program. Medicare payment cuts of this magnitude will greatly undermine 340B hospitals’ ability to continue programs designed to improve access to services – which is the very goal of the 340B program.

⁶¹ 82 Fed. Reg. 52,356 (Nov. 13, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-23932.pdf>.

⁶² *The American Hospital Association v. Azar*, Case 1:18-cv-02084, ECF No. 1 (D.D.C. Sept. 5, 2018) (Complaint, available at <https://www.aha.org/system/files/2018-09/180905-complaint-340b-refiling-suit.pdf>); *id.*, ECF No. 2-1 (Plaintiffs’ Memorandum in Support of Their Motion for a Preliminary and Permanent Injunction).

For the reasons provided in our comments to the CY 2018 OPSS final rule and in the recent court filings, which we incorporate into these comments, we urge CMS to reverse the policy and for CY 2019 to pay ASP plus 6 percent for these section 340B drugs, as it did for CY 2017 and prior years.

Expansion of 340B Payment Policy. CMS proposes, for CY 2019, to extend its flawed policy to 340B hospitals' nonexcepted off-campus PBDs. Separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program and furnished by nonexcepted PBDs would be reimbursed at a rate of ASP minus 22.5 percent, according to the proposed rule. The proposal reverses CMS's earlier position that the payment cut of ASP minus 22.5 percent would not apply to 340B drugs furnished in nonexcepted off-campus PBDs because those drugs were no longer considered covered-OPD services. CMS rationalizes that the expansion of the 340B Medicare payment policy is based on its claim that the difference in the payment amount for 340B-acquired drugs furnished in excepted and nonexcepted off-campus PBDs creates an incentive for hospitals to move drug administration services for these 340B-acquired drugs to nonexcepted PBDs. CMS, however, offers no data or other evidence to support this claim. The agency estimates that this payment change would result in a payment cut of \$48.5 million in CY 2019, but provides no data to support this estimate.

CMS cites section 1833(t)(21)(C) of the Act as its "authority" for applying the 340B policy to nonexcepted off-campus PBDs. This section of the law authorizes the Secretary to identify the "applicable payment system" (other than OPSS) to pay for services provided in nonexcepted off-campus PBDs." CMS has identified the Medicare PFS as the applicable payment system for payment of services in nonexcepted off-campus PBDs, as Congress anticipated. See, e.g., H.R. REP. 114-604(I) (June 7, 2016), available at <https://www.congress.gov/114/crpt/hrpt604/CRPT-114hrpt604-pt1.pdf>, at 10 (explaining that the "practical effect" of section 603 of the Bipartisan Budget Act of 2015 would be that off-campus PBDs would be paid pursuant to the PFS or ambulatory surgical center payment rates – not the "hospital outpatient payment rate"). Since Congress enacted section 1833(t)(21) to exclude nonexcepted off-campus PBDs from OPSS, CMS has used the PFS relativity adjuster to calculate payments as a fixed percentage of the amount determined under the OPSS for a particular item or service, so that payments were aligned with, and roughly equivalent to, physician payments under the PFS.⁶³

In the CY 2017 OPSS/ASC final regulation, CMS stated that "drugs and biologicals that are separately payable under the OPSS ... will be paid in accordance with section 1847A of the Act (that is, typically ASP plus 6 percent), consistent with the payment rules in the physician office setting."⁶⁴ This represented a determination by CMS that for

⁶³ See, e.g., 83 Fed. Reg. 37,046, 37,146 (July 31, 2018) ("As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPSS based on a percentage of the OPSS payment rate, which is determined using the PFS relativity adjuster.").

⁶⁴ 81 Fed. Reg. 79,562, 79,725 (Nov. 14, 2016).

this category of drugs and biologicals, no adjustor was necessary to convert to OPPS payments to approximate the PFS rate; the 1847A rate precisely represents the PFS rate.

In the proposed rule, CMS claims that section 1833(t)(21) allows the agency to pay for drugs and biologicals acquired under the 340B program at a rate that is not an approximation of the rates physicians receive under the PFS. That “special” PFS rate, as proposed by CMS, would equal ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program and furnished by nonexcepted off-campus PBDs, which is the nearly 30 percent reduction that it imposed on OPPS drugs beginning in CY 2018. But section 1833(t)(21) explicitly mandates that payments for items and services furnished by off-campus PBDs “shall be made” under the “applicable payment system,” designated as the PFS by CMS. As CMS has previously stated, the PFS rate for the drugs and biologicals at issue is typically ASP plus 6 percent. **Section 1833(t)(21) does not authorize CMS to pay at a different rate, let alone one that is nearly 30 percent less than the PFS rate.**

It is significant that CMS acknowledges that services, including drugs, furnished at nonexcepted off-campus PBDs are not payable under the OPPS.⁶⁵ Instead, according to CMS, these drugs are paid in the same way as Part B drugs in other nonhospital settings, typically ASP plus 6 percent.⁶⁶ Payment at ASP plus 6 percent is consistent with the statutory purpose of section 1833(t)(21), which is to bring reimbursements for these drugs furnished at nonexcepted off-campus PBDs in line with the reimbursement for drugs under the PFS. **Since ASP plus 6 percent is the PFS rate, there is no need to use a relativity adjuster, and there is clearly no authority under section 1833(t)(21) for using the PFS relativity adjuster to bring prices below, in this case far below, those paid under the PFS.**

Therefore, CMS has unlawfully proposed to use section 1833(t)(21) to reimburse 340B-acquired drugs provided by nonexcepted off-campus PBDs at the same reduced rate that it reimburses 340B-acquired drugs under the OPPS in excepted off-campus PBDs: at ASP minus 22.5 percent. Section 1833(t)(21) is quite clear that its entire purpose is that services for nonexcepted off-campus PBD *not* be reimbursed at the OPPS rate. Instead the goal is to reimburse them at the PFS rate. Elsewhere we have explained why CMS has no authority to cut the reimbursements of section 340B drugs by almost 30 percent.

In addition to citing section 1833(t)(21), CMS also argues that it has authority to establish a special PFS rate (ASP minus 22.5 percent) because “OPPS is a prospective

⁶⁵ See 83 Fed. Reg. at 37,143, col. 3 (“As a general matter, under [(t)(21)], applicable items and services furnished by certain off-campus outpatient departments . . . are not [covered] under OPPS.”); *id.* at 37,145 col. 2 (“[N]onexcepted off-campus PBDs are no longer covered outpatient department services and, therefore, are not payable under OPPS.”).

⁶⁶ See 83 Fed. Reg. at 37,145 col. 2 (Separately payable drugs and biologics “are currently paid in the same way Medicare Part B drugs are paid in the physician office.”).

payment system” and the PFS relativity adjuster “is based on a percentage (40 percent) of the amount determined under the OPPS.”⁶⁷ From that, CMS concludes that “we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.” *Id.* – generally ASP plus 6 percent. But that is a non-sequitur. To be sure, OPPS is a prospective payment system, and OPPS payments are subject to various packaging policies and other hospital-specific adjusters and mechanisms, several of which are “replicated under the nonexcepted off-campus PBD site-specific PFS rates.”⁶⁸ But it is also true that CMS uses the relativity adjuster so that the rates under which these services are billed will approximate PFS rates, which are the rates at which it must reimburse. Further, CMS’s establishment of certain “PPS-like” policies for reimbursing for nonexcepted services in nonexcepted PBDs in the CY 2017 OPPS/ASC final regulation was intended to ensure operational feasibility, namely because it determined that it is not operationally feasible for hospitals to bill in exactly the same manner as physician offices⁶⁹.

But the fact that CMS uses the relativity adjuster to translate OPPS rates to PFS rates for nonexcepted off-campus PBD and the fact that PFS rates are subject to certain “prospective payment system-like” adjustments, whether system wide or site specific, does not give CMS unfettered discretion to completely disregard the PFS rate for drugs and biologicals, dictated by sections 1842(o)(1)(C) and 1847A of the Act. Since it designated the PFS rate as the “applicable payment system” under the statute, CMS must reimburse hospitals at that rate for separately payable drugs and biologicals, including those eligible for 340B discounts. **CMS might “believe” that it has “flexibility” to adopt a *sui generis* PFS rate for 340B-acquired drugs and biologicals, but that “belie[f]” does not make it so, and is wrong, and the policies adopted pursuant to that “belie[f]” are unlawful.**

For an agency’s action to be valid, it must have statutory authority to take the action at issue.⁷⁰ CMS’s imposition of a *sui generis* PFS rate for non-excepted off-campus PBDs fails this requirement, because the statute expressly requires that payments for items and services furnished by such facilities “shall be made” under the “applicable payment system” (the PFS). The statute does not leave any gap for the agency to fill; to the contrary, it imposes an express requirement that CMS has flouted.⁷¹

⁶⁷ 83 Fed. Reg. at 13,146.

⁶⁸ 83 Fed. Reg. at 13,145.

⁶⁹ 81 Fed. Reg., (Nov. 14, 2016), pages 79720 to 79729, (<https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf>).

⁷⁰ See, e.g., *Am. Library Ass’n. v. F.C.C.*, 406 F.3d 689, 691 (D.C. Cir. 2005) (“It is axiomatic that administrative agencies may issue regulations only pursuant to authority delegated to them by Congress.”).

⁷¹ See, e.g., *Loving v. I.R.S.*, 742 F.3d 1013, 1016-22 (D.C. Cir. 2014) (holding that Congress’s conferral on the IRS of authority to “regulate the practice of representatives of persons before the Department of the Treasury” did not confer authority to regulate tax preparers); *Aid Ass’n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1175-78 (D.C. Cir. 2003) (holding that the Postal Service exceeded its “statutory authority” by excluding “insurance-related” mailings from nonprofits’ reduced mailing rates).

Failure to Provide Sufficient Analysis for the Continuation of the CY 2018 Policy. In addition to the concerns cited above, CMS has failed to provide sufficient access to data, methodology or analysis to allow the public to assess and replicate the proposed CY 2019 340B payment policy. In fact, it appears that CMS did not conduct any analysis of the impact of the CY 2018 reimbursement changes for the drugs acquired under the 340B program for the affected 340B hospitals as it prepared the CY 2019 OPPS proposed rule. Although CMS finalized the 340B policy as budget neutral in 2018, the agency has provided no evidence in the CY 2019 proposed rule that it performed any impact analysis for the 340B policy in order to ensure that the adjustment to the OPPS conversion factor was correct. No other conclusion can be made except that CMS did not perform the necessary impact analysis. **On this point, the AHA recommends that, if CMS decides to continue the 340B payment policy, CMS should annually ensure that the 340B policy remains budget neutral by recalculating the policy's impact to make certain the conversion factor properly adjusts for budget neutrality. As such, CMS also should annually calculate a budget-neutral adjustment for the 340B policy.** This approach is consistent with other budget-neutral policies included in OPPS, such as wage index, outliers, rural sole community hospital adjustment, and cancer hospital adjustment for which adjustments are made via the OPPS conversion factor.

BIOSIMILAR BIOLOGICAL PRODUCTS: PROPOSED CHANGE IN PAYMENT POLICY FOR 340B-ACQUIRED BIOSIMILAR PRODUCTS

The AHA supports this proposal and agrees that payment for biosimilar products should be based on their own ASP data.

For CY 2019, CMS proposes to change how the payment for 340B-acquired biosimilars is calculated. CMS proposes to pay nonpass-through biosimilar biological products acquired under the 340B program at ASP minus 22.5 percent of the *biosimilar's own* ASP instead of the biosimilar's ASP minus 22.5 percent of the *reference product's* ASP.

According to the Food and Drug Administration (FDA), a reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared.⁷² In general, the reference product's ASP has a higher price than the biosimilar's own ASP. In proposing this change in the payment calculation, CMS explains that commenters expressed concern that the current policy was unfair because it subtracted off the higher reference product price rather than off the price that hospitals were actually paying.⁷³ **AHA agrees with this proposal and urges CMS to adopt it, although the AHA continues to object to CMS's overall 340B payment policy and proposed expansion to nonexcepted PBDs.** Here CMS recognizes the unfairness in

⁷²<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581282.pdf>.

⁷³ 83 Fed. Reg. (July 31, 2018), p. 37123 <https://www.gpo.gov/fdsys/pkg/FR-2018-07-31/pdf/2018-15958.pdf>.

the payment calculation for 340B-acquired biosimilars while ignoring the inherent unfairness in the overall 340B payment policy.

PART B DRUGS: APPLICATION OF AN ADD-ON PERCENTAGE FOR CERTAIN WHOLESALE ACQUISITION COST (WAC)-BASED PAYMENTS

Currently, Medicare reimburses new Part B drugs for which ASP price data are unavailable during the first quarter of sales at the rate of 106 percent of WAC. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. CMS proposes to reduce payment for certain new Part B drugs and biologicals from the rate of 106 percent of WAC to 103 percent of WAC. Specifically, the proposed reduction would apply to drugs and biologicals where ASP price data are unavailable during the first quarter of sales and in circumstances when Medicare Administrative Contractors (MAC) determine pricing for new drugs that do not appear on the ASP pricing files. CMS states that this proposal is consistent with a recommendation included in the FY 2019 President's Budget Proposal and MedPAC's June 2017 Report to Congress.

The AHA opposes this proposal because it would unfairly shift the burden for the high list prices imposed by drug manufacturers onto hospitals and physicians.

Further, with the Medicare 2 percent sequestration still in effect, payment for drugs and biologicals would effectively be reduced to a level far lower than proposed by CMS. We are concerned that such a significant reduction in payment could negatively impact the ability of some providers to afford these new WAC-priced drugs. It also would not account for the growing pharmacy overhead costs, including drug handling and storage costs, that the WAC add-on percentage was intended to cover.

Finally, we note that MedPAC proposed this WAC policy as part of a larger package of Part B drug recommendations, including a recommendation for improving ASP data reporting. Specifically, only drug manufacturers with Medicaid rebate agreements are required to report their ASP data, and some manufacturers fail to do so in a timely manner. MedPAC's June 2017 report recommended that Congress require all Part B drug manufacturers to report ASP data, and also give the Secretary the authority to apply penalties to manufacturers who do not do so. **The AHA supports efforts to improve ASP data reporting by manufacturers and encourages CMS to pursue this approach in order to ensure that timely and accurate ASP data are available for rate setting.**

PACKAGING POLICY FOR NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SUPPLY

In response to a recommendation in the President's Commission on Combating Drug Addiction and the Opioid Crisis, CMS proposes to un-package and pay separately for non-opioid pain management drugs that function as surgical supplies when they are

furnished in the ASC setting. The drug that is currently utilized in ASCs for which CMS proposes separate payment is Exparel (bupivacaine/lidocaine injected at the surgical site), which is reported with HCPCS code C9290. CMS believes the proposed change would incentivize ASCs to use non-opioid pain management drugs with surgical procedures, instead of opioids (which would remain packaged if furnished in a surgical procedure), and is responsive to the Commission's recommendation. However, the agency does not propose to pay separately for these drugs in hospital outpatient departments.

The AHA appreciates that CMS is engaging stakeholders to investigate novel strategies to address the opioid crisis. We agree that stemming the tide of this epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain.

The AHA agrees that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and therefore warrants separate payment under both the OPPS and the ASC payment system. Therefore, we support this proposal but also recommend that CMS similarly un-package Exparel and other non-opioid pain management treatments in HOPDs. Based on feedback from our members, the AHA agrees that this strategy has the potential to incentivize use of non-opioid pain management drugs in all settings in which outpatient surgery and other outpatient services involving pain management is furnished (such as in the ED). While certainly not a solution to the opioid epidemic, un-packaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-standing practice patterns without major negative consequences.

Similarly, AHA supports un-packaging other non-opioid treatments including drugs, devices and therapy services that are not currently separately payable in both the ASC and HOPD setting. Specifically, we would support separate payment for continuous infusion pumps, as our members suggest that this would be a helpful approach to increase the usage of these non-opioid therapies. For example, the "On-Q" pain relief system is a portable pain system that provides non-opioid local anesthetic medication to the site of the pain. Its purpose is the same as Exparel's, to deliver relief at the site of the pain rather than by a systemic pain reliever. It also prevents the side effects that many people experience from oral medications. Other drugs that should be considered for separate payment are intravenous (IV) Ibuprofen and Ofirmev (IV Acetaminophen). Our members also have suggested that CMS consider separate payment for Polar ice devices that use ice and water for post-operative pain relief after knee procedures. In addition, therapeutic massage, THC oil applied topically, acupuncture, and dry needling procedures are very effective therapies for relief of both post-operative pain and long-term and chronic pain.

PROPOSED PAYMENT ADJUSTMENT POLICY FOR RADIOISOTOPES DERIVED FROM NON-HIGHLY ENRICHED URANIUM (HEU) SOURCES

CMS proposes to extend the \$10 per dose payment adjustment for hospitals that use technetium-99m (Tc-99m) – the radioisotope used in the majority of diagnostic imaging services – when it has been produced in reactors that do not use HEU. Under this policy, in place since CY 2013, hospitals report HCPCS code Q9969 once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources. This payment adjustment is intended to support a longstanding federal policy to eliminate reliance on reactors outside the U.S. that produce the more dangerous weapons grade HEU and to promote the conversion of all medical isotope production to safer non-HEU sources.

The AHA supports this extension. However, as we warned in our CY 2013 comments, without changes to reflect the true cost differential between HEU and non-HEU, we do not believe that hospitals will make widespread use of this policy. Therefore, in coordination with nuclear pharmacies regarding this issue, we urge CMS to adopt payment reflecting their assessment of a \$30 reimbursement level for HCPCS code Q9969 as an adequate incentive.⁷⁴ Indeed, the conversion rate to non-HEU from HEU in Medicare has been very slow, and has not kept pace with the broader marketplace. Specifically, the broader market has converted about half of their doses to non-HEU, while less than 10 percent of procedures under Medicare use non-HEU in 2015.⁷⁵

When the reimbursement was first proposed for CY 2013, CMS anticipated that the conversion to non-HEU sources would be completed by 2018. However, the conversion has been much slower than that, and the Nuclear Energy Agency now anticipates that the conversion will not be complete until 2020.⁷⁶ Further, while some domestic non-HEU production is starting to get up and running, we anticipate that this will be a small contribution to the overall non-HEU supply, and that the non-HEU pipeline will continue to be plagued by supply chain problems.

Additionally, the costs associated with producing non-HEU are higher than those to produce HEU, and our members see a significant cost differential. The additional payment of \$10 per dose, which was finalized for CY 2014 but which has never been updated for inflation, remains inadequate to incentivize hospitals to change their current practices and transition purchases to non-HEU sources. The reimbursement does not cover the costs passed on to hospitals from the various levels of the supply chain, including the producer, the generator manufacturer and the nuclear pharmacy.

⁷⁴ See comment of UPPI.

⁷⁵ National Academies of Sciences, Engineering, and Medicine. 2016. Reducing the Use of Highly Enriched Uranium in Civilian Research Reactors. Washington, DC: The National Academies Press. <https://doi.org/10.17226/21818>.

⁷⁶ <https://www.oecd-nea.org/cen/docs/2018/sen-hlgmr2018-3.pdf>.

Hospitals would welcome the opportunity to support this policy goal, but cost pressure makes it difficult.

EXCLUSION OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCs FROM C-APC PACKAGING

CMS proposes to exclude procedures that are assigned to new technology APCs from being packaged into comprehensive APCs (C-APCs) because of a concern that packaging payment reduces the number of claims for the new technology procedures that are available for APC pricing. The proposed rule indicates that packaging in this circumstance is contrary to the objective of the new technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

The AHA agrees that procedures assigned to new technology APCs should be excluded from C-APC packaging in order to have sufficient claims data available for rate-setting and assignment to appropriate clinical APCs.

EXTENSION OF TRANSITION POLICY AND REMOVAL OF CLAIMS FROM PROVIDERS USING COST ALLOCATION METHOD OF “SQUARE FEET” TO CALCULATE CCRs USED TO ESTIMATE COSTS WITH THE APCs FOR CT AND MRI

In the 2014 OPSS final rule, CMS created distinct cost-to-charge ratios (CCRs) for implantable devices, magnetic resonance imaging (MRIs), computerized tomography (CT) scans, and cardiac catheterization. However, in response to public comment, CMS did not include providers that use a cost allocation method of “square feet” to estimate costs associated with the CT and MRI APCs because of concerns about the lack of accuracy of this particular method. CMS indicated that it would provide hospitals with four years to transition to a more accurate cost allocation method and use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018. However, CMS opted to continue the transition in 2018. Now, in this CY 2019 proposed rule, CMS presents data showing that if the agency were to end the transition (i.e., use cost data from all providers, regardless of their cost allocation method), the result would be significant reductions in payment for CT, MRI and other imaging services.

Although CMS has appropriate imaging CCRs to use for determining payment, it proposes to extend the policy of excluding providers that use the square foot cost allocation methodology in calculating the OPSS relative weights for one additional year, through 2019. However, the agency does not believe another extension in 2020 will be warranted and expects to determine the imaging APC relative payment weights for 2020 using cost data from all providers, regardless of the cost allocation method employed.

The AHA supports CMS's proposal to extend its transitional policy through 2019 and encourages the agency to continue to educate providers about the benefits of switching to a more accurate cost allocation method.

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR T) THERAPY

CAR T therapy is a new cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. As a new technology involving multiple steps across potentially different providers, it is important that appropriate clinical codes be available to report, identify and correctly reimburse the different component services involved in providing CAR T therapy.

Recently, the American Medical Association approved four CAR T-related category III CPT codes, effective Jan. 1, 2019. These codes capture the harvesting of blood-derived T lymphocytes, preparation of the cells (e.g., cryopreservation, storage), receipt and preparation of CAR T cells for administration, and administration. In addition, the National Uniform Billing Committee (NUBC) approved a new revenue code and value code for reporting cell/gene therapy services, including CAR-T. The new codes, which take effect April 2019, would capture services associated with the acquisition of the cells, storage and infusion/insertion of the manipulated biologic (modified cells). They also would provide CMS and other health plans with an opportunity to examine the associated costs directly related to these therapies.

Given the newness of the CPT, revenue and value codes, there is currently a potential overlap with existing Q codes if they are not revised to exclude the clinical services covered by the new codes. To our knowledge, HCPCS Q or J codes have not been revised. **We urge CMS to coordinate across relevant CMS departments and decision-makers to ensure coding, billing, cost reporting and payment decisions for CAR T therapy are aligned and consistent. Instructions should then be provided to guide the correct reporting of the corresponding component services involved in providing CAR T therapy. Such guidance also should include the proper reporting of dosage for pediatric versus adult indications.**

HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes to remove a total of 10 measures from the OQR program – one removed starting with the CY 2020 payment year (which is based on 2018 provider performance) and nine more removed starting with the CY 2021 payment year (based on 2019 performance).

Measures for Removal. The AHA supports CMS’s proposals to remove 10 measures. We appreciate CMS’s efforts to remove measures that provide little meaningful information on quality of care and do not support ongoing hospital quality improvement efforts. We agree that the criteria used to identify measures for removal – i.e., a lack of scientific link between the measure and improved patient outcomes or “topped out” national provider performance – are appropriate. In particular, we applaud CMS for removing structural measures like OP-12 (The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data) and OP-17 (Tracking Clinical Results between Visits) that do not directly assess quality of care or patient outcomes.

However, CMS could do even more to remove measures that do not encourage improvements in hospital quality. First, the agency could immediately remove the nine measures it is proposing to remove in 2020. If they are not contributing to better care, there is no reason to retain them for one more year. Four of the 10 measures proposed for removal have either lost endorsement by the National Quality Forum (NQF) or never received endorsement in the first place; similarly, four of the eight measures proposed for removal from the ASC Quality Reporting Program (ASCQR) also lost NQF endorsement. NQF uses four criteria to assess a measure for endorsement: importance to measure, scientific acceptability, usability and relevance, and feasibility to collect. Endorsed measures are subject to periodic (approximately every three years) review where they are re-evaluated against these criteria. If measures no longer meet these criteria, NQF may decide to remove its endorsement.

In short, removal (or absence) of NQF endorsement indicates that a measure lacks one or more of the key criteria listed above. Measures that do not contribute meaningfully to patient care and/or are scientifically unsound, irrelevant, and difficult to collect should not be included in Medicare quality reporting programs. **Thus, the AHA believes that lack of NQF endorsement should be considered as a ninth measure removal factor.** Like the other removal factors, lack of NQF endorsement would not automatically result in a measure’s removal; a measure may be retained if it addresses an important area of care not otherwise evaluated or if removing the measure would result in decreases in quality. However, the NQF endorsement criteria address multiple elements not otherwise captured in the current set of measure removal factors.

With this in mind, **the AHA believes that there are other measures in the OQR that should be considered for removal as they have lost NQF endorsement or were never endorsed.** These measures include:

- OP-2: Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival (*endorsement removed January 2016*);
- OP-8: MRI Lumbar Spine for Low Back Pain (*endorsement removed May 2017*);
- OP-10: Abdomen CT – Use of Contrast Material (*never endorsed*);
- OP-22: Left Without Being Seen (*endorsement removed May 2012*); and

- OP-33: External Beam Radiotherapy for Bone Metastases (*endorsement removed March 2018*).

OQR Measures and Topics for Future Consideration. Recognizing that removing additional measures would leave the OQR with few measures, the AHA recommends that CMS continue to rely upon its Meaningful Measures framework to identify areas not otherwise addressed by measures currently in the OQR. For example, the OQR has no measures that address mental health (including preventive care and screening) or management of chronic conditions in the outpatient setting. Measures that address these ongoing, non-acute patient needs could encourage the integration of behavioral health into primary care and result in treatment that addresses the whole patient.

INPATIENT QUALITY REPORTING (IQR) PROGRAM

In addition to proposed provisions for the OQR, the rule also contained a provision for the IQR regarding the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. In last year's final rule, CMS removed previously adopted pain management questions and incorporated new Communication About Pain questions out of an abundance of caution in light of the nationwide opioid epidemic; stakeholders had expressed concern that the previous questions inadvertently pressured clinicians to prescribe opioids in order to achieve better scores from patients regarding pain management. Rather than asking about whether pain was controlled, the Communication About Pain questions ask how often hospital staff talked to patients about their pain and how to treat it.

Since finalization of these questions, CMS has received feedback that some stakeholders believe the questions could potentially pressure hospital staff to prescribe more opioids. In addition, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of these questions. Although CMS asserts that the agency is unaware of any scientific studies that support an association between scores on the Communication About Pain questions and opioid prescribing practices, it is proposing to remove these questions beginning with January 2022 discharges.

The AHA agrees that there is a lack of reliable evidence that clinicians prescribe more opioids in order to improve scores on the HCAHPS Communication About Pain questions. However, we also understand that CMS programs can significantly influence trends in the opioid epidemic and thus agree it is prudent to remove the Communication About Pain questions until we can better understand the relationship between these questions and prescribing practices. As CMS notes in the rule, pain management is a critical part of patient care, and hospitals play a vital role in influencing not only acute pain management but also long-term pain control and functional outcomes following hospital procedures. Because of this, we encourage CMS to engage with hospitals, clinicians, measure developers and researchers to explore a range of approaches to assessing how well hospitals are

addressing pain management in the hospital setting. These approaches could include further revisions to the pain questions in HCAHPS, or the use of other measurement approaches.

ASC PAYMENT UPDATE PROPOSAL

For CYs 2019 through 2023, CMS proposes to update the ASC payment system using the hospital market-basket update rather than the Consumer Price Index for all urban consumers (CPI-U). CMS cites several advantages, including that an alternative update factor could stabilize the differential between the OPPS payment and the ASC payment and encourage the migration of services to lower cost settings as clinically appropriate. The agency acknowledged concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy or establish an ASC-specific market basket. CMS seeks comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs.

Medicare payment in different settings should reflect the underlying costs and the types of patients served. However, given the absence of any national set of ASC cost data, it is impossible to determine whether using the hospital market-basket update is appropriate for ASCs. As such, we believe it is premature to use the hospital market-basket to update payments for ASCs. **We urge CMS not to finalize the five-year experiment of using the hospital market basket to update payments for ASCs, but instead to work expeditiously with ASC stakeholders to develop and implement a minimally burdensome way to collect ASC costs.**

We note that every year since 2010, MedPAC has recommended that ASCs be required to submit cost data to CMS. We are encouraged by CMS's statement in the proposed rule that it intends to assess whether it would be feasible to collect ASC cost data in a minimally burdensome manner and that it could propose a plan to collect such information in the future. We urge the agency to move forward with this plan expeditiously. Consistent with MedPAC's views stated in its [March 2018 Report to Congress on Medicare Payment Policy](#), we believe that, like all other facility providers, it should be feasible for ASCs to provide cost information to CMS. In the report, MedPAC suggests several possible streamlined cost-collection processes that would not place a large burden on ASCs and outlines the minimal cost data that would be need to be collected in order to determine an appropriate input price index for ASCs. CMS could use this information to examine the cost structure of ASCs and determine whether the Medicare hospital market basket index is an appropriate proxy for ASC costs or an ASC-specific market basket should be developed.

While it is not yet possible to directly compare an ASC's cost structure with that of a hospital, **there is evidence suggesting that the Medicare beneficiaries cared for in**

ASCs are different and less costly than those in HOPDs. According to MedPAC's analysis⁷⁷ of 2016 Medicare claims data, compared to ASCs, HOPDs treat:

- More beneficiaries dually eligible for Medicare and Medicaid;
- More African American beneficiaries;
- More beneficiaries eligible for Medicare due to disability (under age 65);
- More beneficiaries who are 85 years old or older; and
- Beneficiaries who are more medically complex than patients treated in ASCs (as measured by differences in average patient risk scores).

The AHA has also conducted an analysis⁷⁸ comparing beneficiaries in ASCs to those in HOPDs with similar findings to MedPAC, thus indicating that patients who are too medically complex for ASCs are treated in HOPDs. In addition, our analysis provides evidence that compared to ASCs, HOPDs treat more beneficiaries from areas with lower socioeconomic status (as indicated by median income, poverty and educational attainment), beneficiaries with more prior medical care use (e.g., prior ED visit or inpatient stay) and those with more severe comorbid conditions. These findings suggest that physicians refer more complex patients to HOPDs for safety reasons, as hospitals are better equipped to handle complications and emergencies. Further, these differences in patient characteristics are associated with greater patient needs and higher treatment costs in HOPDs than in ASCs. **The AHA believes that such data should also be factored into the determination of whether the hospital market-basket update is suitable for ASCs.**

PROPOSED ADDITIONS TO THE LIST OF ASC-COVERED SURGICAL PROCEDURES

CMS proposes to update the definition of "surgery" to include "surgery-like procedures" in order to include services described by HCPCS codes outside the surgical CPT code range as procedures that may be performed in an ASC. These procedures are currently paid under OPPS but are not on the list of ASC-covered surgical procedures. Using this proposed revised definition of surgery, CMS conducted its annual review to assess which procedures should be added to the ASC-covered procedures list.

CMS proposes to add 12 diagnostic cardiac catheterization procedures (CPT codes 93451-93462) to the list of covered surgical procedures that the agency believes could be safely performed in the ASC setting and would not require an overnight stay. The agency notes that although these procedures involve blood vessels that could be considered major, it believes these procedures are similar to other procedures currently on the ASC list, and that they may be appropriately performed in an ASC.

⁷⁷ MedPAC March 2018 Report to Congress: Medicare Payment Policy, pages 132-133.

⁷⁸ KNG Health Consulting LLC analysis "Comparing Patient and Provider Characteristics: Ambulatory Surgical Center vs Hospital Outpatient Department", May 5, 2016.

The AHA urges CMS not to finalize its proposal to add these diagnostic cardiac catheterization procedures to the list of ASC-covered procedures because they may impose a significant safety risk to Medicare beneficiaries when performed in an ASC. It is not uncommon for a diagnostic cardiac catheterization procedure to reveal blockages in the coronary arteries that require immediate intervention, such as angioplasty with or without the placement of a stent. However, these interventional procedures, such as stent placement, atherectomy and angioplasty, are not currently covered ASC procedures. Thus, the procedure would need to be concluded and the beneficiary transferred to a hospital for the interventional procedure. This could require emergency transport, or, at the very least, upon completion of the diagnostic procedure and after a period of recovery, the beneficiary would need to be referred to the hospital for the interventional procedure. Performing two separate procedures doubles the risks to the beneficiary, such as possible damage to the artery where the catheter was inserted, heart attack, stroke, bleeding and bruising.

In addition, we believe such a scenario reflects CMS's previously stated concerns about procedures being delayed in order to circumvent the packaging of services. However, in these circumstances, there would be no other option, as the interventional procedures are not, and should not be, performed in ASCs. At the very least, CMS should evaluate the frequency of diagnostic cardiac catheterization procedures that become interventional procedures to better understand the risks to beneficiaries.

RFI ON INTEROPERABILITY

In this proposed rule, CMS asks for input regarding the opportunity to further advance interoperability of health information through the creation of Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) and conditions for coverage (CfCs) for other providers. CMS invites comments, noting other agency-related initiatives that promote broader adoption of electronic health records (EHRs) systems, and the use of these systems to facilitate communication among the providers caring for individual patients as well as between providers and patients. CMS observes that some of its previous initiatives have resulted in significant advances in the use of EHR systems while others have not yet been finalized, such as the proposed discharge rule of 2015, or have only recently been finalized by CMS and have not yet realized their full impact in terms of changing the delivery of health care. **The AHA strongly opposes creating additional CoPs/CfCs to promote interoperability of health information as described further below.**

Background. **The AHA strongly supports the creation of an efficient and effective infrastructure for health information exchange. This is central to the efforts of hospitals and health systems to provide high-quality coordinated care, support new models of care and engage patients in their health. However, we do not believe a new mandate tied to CoPs is the right mechanism to advance health information exchange.** We are making progress on information exchange, due to the

investment and concerted efforts of hospitals and health systems. According to AHA 2016 survey data, 93 percent of hospitals and health systems provide patients with the ability to access their EHRs online, up from only 27 percent in 2012. Consumers also can download their information and choose to send it to a third party. Hospitals and health systems increasingly offer other online services, such as prescription refills, appointment scheduling, and secure messaging that make care more convenient. AHA data also show that hospitals and health systems have deployed systems to share health records with other providers of care to better support care coordination and transitions across settings of care. Seventy-one percent of hospitals and health systems share clinical or summary of care records with ambulatory care providers outside their system, up from 37 percent in 2012.

However, the commitment of health care providers is not sufficient by itself to create interoperability. The technical and organizational infrastructure must be available and allow for efficient exchange, and all parties to exchange must be using compatible technology in consistent ways. All of this must be achieved in a way that simultaneously allows the free flow of information to others who have a legitimate reason to have the information while protecting the information from hackers and others with nefarious intent. **We urge CMS to recognize the impediments to information sharing described below and address them directly. We do not believe that creating a CoP or CfC that would apply to only one set of actors is an appropriate strategy. Further, it is not clear that such requirements would have any greater impact on interoperability than the existing federal requirements to share information, but could have unfortunate consequences for some hospitals and communities.**

The Imposition of CoPs and CfCs has Practical Implications. CoPs/CfCs are taken seriously by health care providers because failure to comply carries a heavy penalty. Declaring a hospital to be out of compliance with the CoPs can be extremely disruptive for patients, providers, and communities, as it means that a hospital could be removed from these programs and would no longer be able to care for Medicare or Medicaid patients. The penalty of not meeting an interoperability CoP is too stringent, especially given that the journey towards interoperability is still underway. Moreover, use of the CoPs/CfCs to promote interoperability are misguided for the following three reasons:

1. **CoPs/CfCs are requirements to ensure safe health care delivery, and care can be delivered safely without the interoperability of EHRs.** The Social Security Act (Title 18, Section 1861) authorizes the Secretary to establish requirements that are necessary for the health and safety of those being cared for in hospitals and other organizations. Clearly, the timely exchange of information among providers caring for an individual is an important step forward in ensuring that the relevant clinical information about the patient's diagnoses and treatment plan are in the hands of those providing care. This can help prevent errors in care as well as ensure the continued provision of the right care at the right time to patients. Because patients and their designated family members are a critical part of the care team, it is

important that they, too have access to the patient's information in an accurate, complete and timely manner to ensure high-quality, safe care.

We agree that interoperable EHRs should be capable of achieving information exchange. No other form of communication has the potential to enable such a complete set of information that can easily be searched by the recipient so that vital facts can quickly be identified and used. To the extent EHRs are capable of this type of information exchange, hospitals are already using them, and there already are substantial incentives in place for hospitals and some other providers through the now Promoting Interoperability Program (formerly known as Meaningful Use), as noted below. It is not clear that a CoP or CfC would increase the feasibility of information sharing by these health care organizations. Since neither the CoPs nor the CfCs apply to government agencies, patients or others with whom hospitals and other providers would be trying to exchange information, we believe such requirements would have limited effect in promoting interoperability. **Instead, the AHA urges CMS to focus its attention on resolving problems created by the lack of a fully implemented exchange framework, adoption of common standards and incentives for EHR and other information technology (IT) vendors to adhere to standards.**

- 2. It is premature for CMS to consider imposing COPs/CfCs until the barriers to exchange have been addressed and all of those affected by the requirements can, in fact, achieve compliance.** Compliance is impossible when there is no commonly accepted operational definition of interoperability and no commonly accepted metrics for interoperability. The implementation of EHR in general acute care hospitals is widespread. Our latest survey data from 2016 show that 96 percent of hospital have a certified EHR. Similarly, many physician practices have implemented EHRs that are compliant with the requirements imposed on physician practices for achieving meaningful use. However, the uptake of EHR systems in other parts of health care is less robust because other care providers did not have the same incentives provided under Meaningful Use.

Other barriers to interoperability exist as hospitals and health systems try to electronically send, receive, or query patient health information to and from other care settings or organizations. In responding to the AHA survey, hospitals identified the following challenges:

- The information sent is not useful to recipients;
- The workflow required to enter and send information from their EHR is cumbersome;
- Identifying the correct patient between systems is difficult because there is no single patient identifier; and
- Exchanging information across different vendor platforms is difficult.

Almost half of respondents noted they experience greater challenges exchanging information across different vendor platforms and more than one-third report difficulty matching or identifying the correct patient between systems. Some provider organizations, particularly those that are small or that serve a large number of patients with limited insurance coverage, simply do not have the resources to invest in expensive EHR systems. Regardless of why some providers do not have EHR systems, it is extremely difficult to achieve interoperability with those who are not using a system.

Further, although the Office of the National Coordinator for Health Information Technology (ONC) was charged with developing standards for collecting information in EHRs so that it could be readily exchanged with other providers, those standards have yet to be consistently implemented across systems in ways that make exchange efficient and effective. This is largely the reason why it is challenging to exchange information between providers on two different types of EHRs and, in some cases, between providers using EHRs manufactured by the same company, but with different versions and different installations. Considerable efforts are underway, and progress is being made. However, exchange across settings, such as between two hospitals or a hospital and a post-acute care setting or clinician office, is very challenging. And, without the exchange infrastructure discussed below, can require expensive point-to-point interfaces.

- 3. Modifications of the CoPs/CfCs require clear and unambiguous evidence that compliance could be readily seen by a survey team charged with assessing the facility's compliance.** Health care organizations want to be in compliance with the CoPs/CfCs at all times. They view this as their obligation to the patients they serve. Yet, to be in compliance, they must have a clear and unambiguous understanding of what is expected and how they are to be judged as being in compliance. Since there are no clear, common metrics of interoperability, and since the survey team only visits the facility they are assessing, what evidence would they be looking for to assess the ability of the hospital or other provider to transmit/receive patient information to/from other providers, state or federal agencies, or others with whom they are to achieve interoperable exchange of information? Further, what would surveyors rate as full compliance with the requirement? If the hospital or other provider can transmit the information, but the intended recipient cannot receive it, has interoperability been achieved? If not, is it right or fair to hold the hospital or other provider accountable for the other organization's failure to be able to receive the data, especially since failure to comply with a CoP/CfC on interoperability can put a hospital or other organization in jeopardy of losing its ability to participate in Medicare and Medicaid. This seems to be too steep a penalty for not being able to communicate with another entity, especially if that failure is not within the hospital's ability to correct.

We also are concerned about the costs of compliance. Based on our survey to understand the regulatory costs associated with health IT, on average, surveyed

hospitals spend \$760,000 annually meeting regulatory requirements, most of which is being used to hire and maintain additional staff. Hospitals made additional IT investments averaging \$411,000 during the year for the Promoting Interoperability Program, an investment more than 2.9 times larger than that made in any other area. Small provider organizations or those serving communities with few resources may simply be unable to afford the necessary investment in EHR technology, personnel and support systems to sustain this kind of interoperability.

The AHA urges CMS not to move forward with a plan to require interoperability as a CoP/CfC until such time as it is reasonably feasible to efficiently and effectively achieve such communication across the majority of providers delivering health care in a region. Instead, CMS should coordinate with ONC on implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) and other steps needed to create the infrastructure that would support interoperability.

Other Opportunities Exist to Further Interoperability. CMS already holds hospitals accountable for supporting interoperability under the Promoting Interoperability Program. The agency requires hospitals to attest to three separate statements indicating it:

- Did not “knowingly and willfully take action to limit or restrict the compatibility or interoperability” of their certified EHR;
- Have implemented the technology to support “secure and trusted bidirectional exchange” of health information; and
- Have “responded in good faith and in a timely manner” to requests for exchange information from others.

Those failing to attest face significant financial penalties under the inpatient PPS and CAH programs. Further, the specific requirements of the Promoting Interoperability Program promote information sharing across providers and with patients.

Greater Availability of Health IT is Needed in the Post-acute Care Setting to Support Widespread Health Information Exchange. Sharing information across the continuum of care is a priority. Post-acute care hospitals were not included in the EHR Incentive Program yet have worked diligently to identify and deploy technology to support their care delivery and care coordination goals. However, challenges to attainment of this goal persist as post-acute providers vary in size and resources and have more limited options than acute care providers when choosing an EHR related to their size, locations and technology, and implementation costs. **The AHA recommends that CMS not implement a CoP/CfC to increase interoperability across the continuum of care because post-acute care providers were not provided the resources or incentives to adopt health IT. Such a requirement would only be workable if all facilities were afforded the same opportunity to acquire certified EHRs that actually conformed to standards that enable the kind of interoperability CMS envisions.**

An Information Exchange Framework is Necessary to Assess Interoperability Across Settings. We recognize that today's health information exchange landscape is comprised of a complex set of existing networks that include large national networks, regional and state networks and networks maintained by individual EHR vendors. There are initiatives to connect across networks but the work is nascent at this time. **The AHA supports the advancement of and adherence to a framework for interoperability so that the technology and the rules governing the exchange of health information are universally and consistently implemented and the implementation can be clearly demonstrated. We strongly urge CMS and ONC to focus on creating the infrastructure for exchange and continuing to build toward consistent use of standards across vendor platforms.**

Any framework and common agreement must specify minimum standards and essential elements needed to facilitate exchange so that end-users have assurance that all health information exchange networks are following the same rules of the road to ensure that exchange is trustworthy, reliable and efficient. The framework and common agreement should address, among other things:

- The minimum standards and implementation requirements that must be met to ensure efficient exchange, including standards to secure information;
- The permitted purposes for exchange;
- A clear understanding of the means to identify and authenticate participants of an individual exchange;
- A clear understanding of how the identity of individuals will be matched and managed across networks; and
- Assurance that each network will be transparent in the terms and conditions of exchange, including any technical prerequisites and costs of participating in exchange.

On Jan. 5, ONC released the draft TEFCA, which describes a set of legal relationships, governance approaches and types of information exchange that would allow for more efficient and effective sharing of health information across the country. The draft TEFCA puts forward six principles and more than 100 minimum required terms and conditions that would apply to those entities that voluntarily choose to share information under the trusted exchange framework. It also creates a structure for trusted information exchange and sets forward six "permitted purposes" for information exchange – treatment, payment, health care operations, public health, individual access to health information and benefits determination (specific to determining eligibility for disability benefits under the Department of Veterans Affairs and Social Security Administration). It describes three "use cases," representing the ways in which exchange may happen and include:

- A broadcast query to all participants in the exchange asking for information about a specific individual(s);

- A directed query to a specific organization(s); and
- Population level data requesting information about multiple individuals in a single query (with no upper bound provided).

At this time, we understand that work is underway to revise the draft TEFCA in response to stakeholder feedback. **The AHA recommends that CMS postpone initiatives to advance requirements for interoperability prior to the finalization of TEFCA.**

RFI ON PRICE TRANSPARENCY

The AHA is committed to improving patients' access to information on the price of their care and, more specifically, on their out-of-pocket cost obligation. In general, advancing price transparency has been challenging for the health care system due to the inherent uncertainty in the course of disease and treatment, as well as the need to share data and information across multiple payers and providers. For more detailed input, we point CMS to our previous [comments](#) on this issue, submitted as part of our response to the 2019 inpatient PPS proposed rule.

RFI ON LEVERAGING THE AUTHORITY FOR THE COMPETITIVE ACQUISITION PROGRAM FOR PART B DRUGS AND BIOLOGICALS FOR A POTENTIAL CMS INNOVATION CENTER MODEL

CMS solicited comments on a potential demonstration project to test a new way of paying for certain drugs covered under Medicare Part B. Specifically, the agency is exploring whether the reintroduction of a competitive bidding program for separately payable Part B drugs would reduce spending in the program, including beneficiary co-payments. The agency profiled both the Competitive Acquisition Program, which was in operation from 2006-2008, and MedPAC's Drug Value Program model and posed a series of questions to obtain information on the structure of such a demonstration project. CMS seeks information on issues such as: the types of providers and suppliers that should be eligible to participate; the drugs and biologicals that should be included in the program; the types of beneficiary protections that would be needed; and the selection criteria and contract terms for vendors. Finally, CMS expressed interest in whether the program could be structured in such a way so that other payers, such as Medicare Advantage plans or state Medicaid agencies, could participate.

We appreciate the agency's attention to the issue of high-drug prices. This ongoing issue threatens the quality of care and patient access to critical drug therapies. Both patients, and the providers who serve them, are struggling to afford drugs as a direct result of manufacturers' decisions to increase prices for both new and existing drugs. However, as we have [previously commented](#), the competitive bidding approach for some Part B drugs is unlikely to have a substantial impact on drug prices for physicians

practicing in hospital outpatient departments and may simply introduce more burden into the system. First, most hospitals already use a third-party entity to negotiate drug prices on their behalf. Second, many of the negotiation tools that vendors could use to achieve savings, such as step-therapy and formularies, are already widely used within hospitals and health systems. Finally, with respect to new drugs with high launch prices, we are skeptical that these third-party vendors will be able to compel drug manufacturers to reduce prices. Drug manufacturers commonly refuse to negotiate pricing on new drugs for which there is no competition.

We are encouraged, however, by CMS' attention to the potential development of value-based purchasing (VBP) arrangements between purchasers and drug manufacturers. While we also are doubtful that VBP arrangements will lower drug prices to a sustainable level on their own, there is merit in developing these models regardless. Hospitals and health systems have been engaged in various forms of VBP for many years and, while not without challenges, VBP reimbursement models can lead to positive changes in the health care system, such as increased communication and alignment across health care stakeholders. We encourage the agency to serve as a convener to bring together purchasers, including providers, and drug manufacturers to develop such models, which could then be voluntarily pursued in negotiations.

One type of new, high-cost drug for which CMS has expressed particular interest in exploring alternative payment approaches is CAR T therapy. As stated above, CAR T is a cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. CAR T products and associated services are addressed in both inpatient and outpatient payment systems. In the FY 2019 inpatient PPS final rule, CMS finalized CAR T product approval for new technology add-on payments, but declined to finalize any further inpatient payment-related proposals. Instead, the agency referenced this RFI on a potential demonstration program on alternative payment models. However, this RFI relates to drugs and biologics covered under Medicare Part B and does not address drugs such as CAR T which are almost exclusively used in the inpatient setting and therefore covered under Medicare Part A. Therefore, we do not believe this RFI will generate the information the agency would need to develop alternative payment methodologies for CAR T and other similar therapies.

The AHA urges CMS to continue exploring how to adequately capture the cost of providing costly new therapies such as CAR T, recognizing the inherent differences across settings and payment systems. We remain concerned that current payment methods do not sufficiently offset the extraordinary costs associated with providing these therapies, and may ultimately put beneficiary access at risk.

As we stated previously in our FY 2019 inpatient PPS [comment letter](#), in order to protect beneficiary access to CAR T, CMS should consider the following policies for CAR T payment when provided in inpatient settings:

- Use an alternative method of determining the cost of the CAR T therapy that ensures the agency captures cost accurately, such as using the therapy's ASP as price as a proxy for its cost, or using a CCR of 1.0;
- Increase the new technology add-on marginal reimbursement to 100 percent for CAR T; and
- Identify longer-term solutions for these costly new technologies, such as making payment on a pass-through basis.

To further efforts to achieve sustainable drug pricing, we point the agency to our more detailed drug price proposals recommendations [here](#).