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September 27, 2019

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–1717–P, Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals; Proposed Rule (Vol. 84, No. 154), August 9, 2019.***

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) 2020.

America's hospitals and health systems are dedicated to ensuring patients have the information they need to make informed health care decisions, including knowing what their expected out-of-pocket costs will be. However, CMS's proposal mandating the disclosure of negotiated charges between health plans and hospitals is the wrong approach. Instead of helping patients estimate their out-of-pocket obligations, it would introduce confusion and fuel anticompetitive behavior among commercial health insurers in an already highly concentrated insurance industry, seriously limiting the choices available to patients. In addition, the proposed approach would impose substantial burden on hospitals without a corresponding benefit for patients. **While we support increased transparency for patients around their out-of-pocket cost expectations, this proposal misses the mark, exceeds the Administration's legal authority and should be abandoned. Rather, we urge CMS to work cooperatively with providers, health plans, patients and other stakeholders to identify approaches that can better meet patient needs.**

**The AHA also maintains that three additional proposed policies that CMS has included in this rule run afoul of the law and rely on the most cursory of analyses and policy rationales. Taken together, these proposals would have a chilling effect on beneficiary access to care while also increasing regulatory burden. Specifically, the AHA opposes CMS's proposals to:**

- Complete the phase-in of payment reductions for the hospital outpatient clinic visit in excepted off-campus provider-based departments (PBDs) to the "physician fee schedule equivalent" rate of 40% of the OPPS rate;
- Continue the current policy that pays for separately payable drugs acquired through the 340B drug savings program at the rate of average sales price (ASP) minus 22.5%; and
- Implement a prior authorization process for five categories of outpatient department services.

**On the clinic visit policy, we remind CMS that the agency was recently found by the courts to have exceeded its statutory authority when it cut the payment rate for clinic services at excepted off-campus PBDs. As a result, we urge CMS to: (1) immediately restore the higher payment rates for visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts; (2) repay hospitals promptly the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates and; (3) abandon its proposed second phase of the payment cut in 2020. Should the agency move forward with the second phase of the cut, it will cause additional harm to many hospitals, and the AHA intends to continue pursuing its legal remedies.** By proposing to complete the phase-in of the onerous cuts for hospital outpatient clinic visits, CMS has not only undermined clear congressional intent, but has threatened to impede access to care, especially in rural and other vulnerable communities. The AHA has been working to overturn this rule by working with the Congress and through legal action because these cuts clearly exceed the Administration's legal authority. That position has now been affirmed in federal court.

**On the 340B policy, HHS should recalculate the payments due to every 340B-participating hospital that was subject to the reduced OPPS payment for 340B drug claims in 2018 and 2019 to ensure that those hospitals receive the full statutory rate of ASP plus 6% plus interest, and hold non-340B hospitals harmless. Further, as there is no basis for paying hospitals less than the statutory ASP plus 6%, we oppose the proposed continuation of cuts in payments for 340B drugs in 2020.** This would only exacerbate the strain placed on hospitals serving vulnerable communities. The AHA, along with other hospital associations and member hospitals, successfully challenged the previous cuts to the 340B program in court. Now that the court has ruled that those cuts are illegal and exceeded the Administration's authority, we urge CMS to refrain from doing more damage to impacted hospitals with another year of illegal cuts.

**Finally, the AHA opposes CMS's proposal to implement a prior authorization requirement for certain services and urges the agency to withdraw it. This proposal is contrary to law and arbitrary and capricious. As the federal court recently said when addressing CMS's clinic visit policy, "Congress did not intend CMS to use an untethered 'method' to directly alter expenditures independent of other processes. To the contrary, Congress directed that any 'methods' developed under paragraph (t)(2)(F) be implemented through other provisions of the statute." That conclusion applies with equal force to the proposed prior authorization requirement, which means that CMS exceeded its authority because the proposal is contrary to the OPPI statute. In addition, the proposal is arbitrary and capricious because the agency has not established that the increase in volume for these services is "unnecessary." But even if it had, there are several existing processes CMS could use to verify medical necessity instead of imposing a new and costly prior authorization process that runs completely contrary to the agency's goal of reducing regulatory burden. In addition, it is unclear why CMS only proposes to impose a prior authorization process on hospitals, when it is physicians who order and furnish the services that the agency claims have experienced an "unnecessary" increase in volume.**

With regard to other proposed policies included in the proposed rule, the AHA:

- Strongly supports CMS's proposal to change the minimum required level of supervision from direct supervision to general supervision for hospital outpatient therapeutic services provided by all hospitals and critical access hospitals;
- Opposes the removal of total hip arthroplasty (THA) from the inpatient-only list;
- Opposes CMS's proposal to add total knee arthroplasty (TKA) procedure and several coronary intervention procedures to the list of ASC-covered procedures;
- Urges CMS to pay separately for all non-opioid pain management drugs that function as surgical supplies under the OPPI, just as it is proposing to continue to do in ASCs;
- Urges CMS to extend its transitional policy of excluding providers that use the square foot cost allocation methodology in calculating the OPPI relative weights for certain imaging services at least one additional year;
- Recommends that CMS consider adding new comprehensive ambulatory payment classifications (C-APCs) for skin substitute procedures;
- Supports the removal of one quality measure, but recommends against adopting four ASC patient safety measures in the future;
- Supports CMS's proposal to allow grandfathered children's hospitals-within-hospitals to add beds without losing grandfathered status; and
- Does not recommend that CMS finalize any of the agency's possible changes to the laboratory date-of-service exception.

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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, director for policy, at [rschulman@aha.org](mailto: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) 2020**

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## PRICE TRANSPARENCY

CMS proposes to require that hospitals publicly post on the internet a machine-readable file containing both gross charges and “payer-specific negotiated charges” for all items and services. It also proposes to require hospitals to display, in an easy-to-understand format, negotiated charges and certain other information for 300 “shoppable” items and services. The agency points to section 2718(e) of the Public Health Services Act (PHSA), which requires hospitals to make their standard charges publicly available, as authority for this proposal.

While deeply committed to ensuring patients have the information they need to make informed health care decisions, including timely, accurate estimates of their out-of-pocket costs, the AHA strongly disagrees with this proposal. This approach would confuse – not help – patients in understanding their potential out-of-pocket cost obligations, would severely disrupt private contract negotiations between providers and health plans, and exceeds the Administration's legal authority. **We urge CMS to abandon this proposal and instead cooperatively work with providers, health plans, patients and other stakeholders to identify approaches that could better meet patient needs.**

Disclosure of Payer-Specific Negotiated Charges. The AHA previously commented on the Office of National Coordinator for Health Information Technology's (ONC) suggestion that the definition of electronic health information could permit the disclosure of commercial information from contracts that hospitals enter into with health plans.<sup>1</sup> AHA began by reaffirming that its “members strongly support patients having easy access to their health information so that they can be partners in their care” noting that “[o]ur members’ long history working directly with patients to provide price estimates for care suggest that patients look for information on their out-of-pocket costs” not commercial information from contracts.<sup>2</sup> We consequently urged that the focus be on out-of-pocket costs to address the goals of price transparency.

The AHA further commented that ONC lacked the legal authority to require the disclosure of commercial information from contracts and doing so would be an unreasonable interpretation of the relevant statute. We also raised First Amendment concerns with compelling such a disclosure.

In addition to the myriad legal reasons that compelling these disclosures would violate the law, we noted substantial policy reasons for opposing the disclosure, as did other commenters. Among those reasons was that disclosing price information would inhibit competition because it would create a platform for price fixing. “Health plans would

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<sup>1</sup> AHA Comments on Re: RIN 0955-AAOI, 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program: Proposed Rule (Vol. 843, No. 42) June 3, 2019 available <https://www.aha.org/system/files/media/file/2019/06/aha-let-onc-21st-century-cures-act-hit-proposed-rule-6-3-2019.pdf>.

<sup>2</sup> Id.

know what every other health plan was paying and could use that information indirectly to collude and drive prices below competitive levels, thereby reducing the incentives for actual competition in the marketplace, and threatening the viability of some of the nation's most vulnerable hospitals.”<sup>3</sup> AHA's comments on the ONC proposal were underscored by comments from many others, including commercial health insurance companies, one of which warned that such disclosure would lower quality, “impair the movement toward value-based care” and allow “[d]ominant health plans [to] seek and use that information to deter and punish hospitals that lower rates or enter into value-based arrangements with the dominant plan's competitors, thus maintain[ing] their dominance and fostering higher costs of care.”<sup>4</sup>

Likewise, we noted that the Federal Trade Commission (FTC) has been clear on this subject in numerous letters and blogs consistently warning that disclosure of the type of competitively sensitive information “may facilitate collusion, raise prices and harm ... patients ...”<sup>5</sup> AHA also explained that in a letter to Minnesota state legislators, the FTC counseled against disclosure of health plan terms and urged that transparency be limited to “predicted out-of-pocket expenses, co-pays, and quality and performance comparisons of plans or provider.”<sup>6</sup> Similarly, we noted that the Department of Justice's Antitrust Division's recent challenge to commercial health plan consolidation underscored the danger that collusion among commercial health plans would impede innovation and drive prices below competitive levels for vulnerable providers without sharing any of the savings derived from that illegal conduct with consumers.<sup>7</sup>

All of these concerns, and some new ones, apply to the current proposed rule that would require hospitals to make public payer-specific negotiated charges. Once again, we believe that CMS lacks statutory authority to impose these requirements, the agency's interpretation of the relevant statute is contrary to its plain language and unreasonable, and the proposal could violate the First Amendment. In addition, the proposal to require disclosure of negotiated charges could violate the trade secret laws and imposition of civil money penalties (CMPs) on hospitals that fail to make the required disclosures would exceed CMS's legal authority.

Our comments below expand on our legal concerns about the proposal, describe the overwhelming operational challenges posed by the proposed rule, and explain the constructive role that CMS could play in convening stakeholders to address some of the

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<sup>3</sup> Id.

<sup>4</sup> UnitedHealth Group Comments on Re: RIN 0955-AAOI, 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program: Proposed Rule (Vol. 843, No. 42) June 3, 2019 at 15-16.

<sup>5</sup> FTC letter to the Hon. Nellie Pou, April 17, 2007.

<sup>6</sup> FTC letter to the Hon. Joe Hoppe and Hon. Melissa Hortman, June 29, 2015.

<sup>7</sup> “In highly concentrated [commercial health insurance] markets, already-large health plans are less constrained by competition and thus tend to find it more profitable to capture medical savings and increase premiums.” *United States v. Anthem, Inc.*, 855 F.3d 345 (D.C. Cir. 2017) at 30.

challenges in providing patients with the information they actually are seeking: their out-of-pocket costs.

*CMS Lacks Legal Authority to Require Hospitals to Make Public Payer-Specific Negotiated Charges as Well as to Impose Civil Money Penalties for Violations of the Transparency Rules*

I. The statute does not authorize CMS to require hospitals to make public payer-specific negotiated charges.

CMS relies on section 2718(e) of the PHSA<sup>8</sup> to require hospitals to make public their gross charges as well as their payer-specific negotiated charges, including the negotiated charges for 300 shoppable services in a consumer-friendly format. But section 2718(e) does not provide CMS with authority to establish these requirements.

Section 2718(e) authorizes CMS to require hospitals to “establish (and update) and make public (in accordance with guidelines developed by the Secretary) *a list* of the hospital's *standard charges* for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the [Medicare statute].” (Emphasis added.) CMS’s proposal is contrary to the language of the statute and violates the Administrative Procedure Act (APA) on other grounds as well.

A. CMS’s proposal is contrary to the plain language of the statute, which requires hospitals to make public only their standard charges.

CMS’s proposal to require the disclosure of negotiated charges violates the plain language of the statute. Negotiated charges are not standard charges. By definition, a “standard charge” is not privately negotiated and does not contemplate different charges for different payers.

“Standard charges” has long been understood in the hospital field to be a technical term of art that means a hospital’s usual or customary *chargemaster* charge. See *Webster Cty. Memorial Hosp. v. United Mine Works of Am. Welfare & Retirement Funds*, 536 F.2d 419 (D.C. Cir. 1976) (suggesting that, since at least the 1970s, “standard charges” has been understood in the hospital field to mean the usual or customary charge *not including* any negotiated discounts). Indeed, as discussed below, this also is how CMS appears to have interpreted it until quite recently. And with good reason: As a matter of plain language construction, the statute *dictates* this result. Where Congress regulates in a specialized field or area and uses words or phrases with specialized meanings in that industry or area, “[i]n the absence of contrary indication . . . Congress intended it to [give the word or phrase] its established meaning” in the technical art or science to

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<sup>8</sup> 42 U.S.C. § 300gg-18(e).



which Congress has referred.<sup>9</sup> CMS must therefore give the phrase “standard charges” the meaning it has long been ascribed in the specialized context of hospitals. In other words, as a matter of plain language, CMS must interpret “standard charges” to mean the “chargemaster charges.”

Moreover, if Congress intended to require providers to disclose payer-specific negotiated charges, it would have spoken clearly. Congress would not hide such a mandate in vague language of an obscure provision of the statute, because “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.”<sup>10</sup> To the contrary, Congress speaks clearly when it intends to mandate disclosure of such sensitive information — just as Congress did for plans eligible to be on health exchanges in section 1311(e)(3) of the Affordable Care Act (ACA).<sup>11</sup> There, Congress expressly said that, in order to be certified as a qualified health plan, a plan must, among other things, “make available to the public . . . “[i]nformation on cost-sharing and payments with respect to any out-of-network coverage.” Congress was similarly specific in the Sunshine Act when it required disclosure and public reporting of confidential information about manufacturer payments to physicians.<sup>12</sup> Given the highly confidential nature of payer-specific negotiated charges, and the highly controversial nature of requiring its public disclosure, Congress would not authorize CMS to include payer-specific negotiated charges in the definition of standard charges sub silentio.<sup>13</sup>

CMS also cannot justify requiring the publication of payer-specific negotiated rates under the authority Congress gave the agency to develop guidelines for making public a hospital’s list of standard charges. That authority simply cannot be stretched to require publication of multiple lists. Rather, as CMS itself has recognized, the guidelines for making a hospital’s list of standard charges public determine *how* the list is made public — paper copies, on the internet, etc.<sup>14</sup> Thus, the authority “to develop guidelines” for making standard charges public is different from the authority to require hospitals to make public payer-specific negotiated charges.

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<sup>9</sup> *Alabama Power Co. v. EPA*, 40 F.3d 450, 454 (D.C. Cir. 1994) (“In the absence of contrary indication, we assume that when a statute uses such a term, Congress intended it to have its established meaning.”) (internal citations omitted).

<sup>10</sup> *Whitman v. American Trucking Ass’n*, 531 U.S. 457, 468 (2001).

<sup>11</sup> Affordable Care Act, Pub. L. No. 111-148, § 1311(e)(3), 124 Stat. 119, 900; see also *In re Failla*, 838 F.3d 1170, 1176–77 (11th Cir. 2016) (where Congress uses different words or phrase, such “a material variation in terms suggested a variation in meaning.”).

<sup>12</sup> See Social Security Act (SSA) § 1128G.

<sup>13</sup> See, e.g., *Director of Revenue of Mo. v. CoBank, ACB*, 531 U.S. 316, 323 (2001) (“[I]t would be surprising, indeed, if Congress had effected a “radical” change in the law “sub silentio” via “technical and conforming amendments.”).

<sup>14</sup> For example, CMS explained that it had, “effective January 1, 2109, announced the update to our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could be in the form of the chargemaster itself or another form of the hospital’s choice, as long as the information is in machine readable format.” 83 Fed. Reg. 41,144, 41,686 (Aug. 17, 2018).

B. The proposed definition of “standard charges” is unreasonable.

1. Negotiated rates are not standard charges.

Even if the term “standard charges” were ambiguous (which it is not), CMS’s proposed definition still violates the APA because it is unreasonable. In general usage, “standard” means “usual, common or customary.”<sup>15</sup> Payer-specific negotiated charges are not usual, common or customary. They vary year by year, payer by payer and even health plan by plan. Indeed, CMS has defined “charges” to mean “the regular rates established by the provider for services rendered to both [Medicare] beneficiaries and to other paying patients. Charges should be . . . *uniformly applied to all patients* . . . .”<sup>16</sup> And the agency’s rationale for seeking to require that payer-specific negotiated charges be made public undercuts the notion that those charges are standard: CMS wants payer-specific charges to be public precisely because those charges are not standard.<sup>17</sup> It is an oxymoron for CMS to say that payer-specific negotiated charges are *standard* charges.

It also would be unreasonable for CMS to interpret “standard charges” to include payer-specific negotiated charges because “a fundamental rule of statutory construction requires that statutes are to be construed, if possible, in harmony with . . . other applicable statutes.”<sup>18</sup> Yet CMS’s interpretation of “standard charges” would unreasonably (and impermissibly) allow the agency to circumvent statutory protections that Congress set forth under the Freedom of information Act (FOIA) to protect trade secrets and confidential commercial or financial information against broad public disclosure.

In the past, CMS itself has recognized that pricing information can be protected from disclosure under FOIA Exemption 4.<sup>19</sup> CMS cannot circumvent these statutory privacy protections through a creative interpretation of the phrase “standard charges.” As discussed, if Congress had intended to authorize disclosure of such sensitive information, Congress would have said so plainly — and not relied on vague language or ancillary provisions.<sup>20</sup> Even if the phrase “standard charges” were ambiguous, it is unreasonable for CMS to stretch any ambiguity by interpreting the phrase “standard charges” in a manner out of harmony with FOIA, and it is arbitrary and capricious for CMS to propose to mandate the disclosure of highly commercially sensitive information without meaningfully weighing the full scope of the competitive harms that are likely to result from such compelled disclosures. At bottom, CMS appears to be attempting to do something indirectly that it could not do directly: If CMS could require hospitals to provide their confidential price information to the government (which it cannot), that

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<sup>15</sup> See, e.g., <https://www.dictionary.com/browse/standard>.

<sup>16</sup> Provider Reimbursement Manual, No 15-1, ch. 22, § 2202.4. (Emphasis added.)

<sup>17</sup> See, e.g., 84 Fed. Reg. 39,175, 39,577 (Aug. 9, 2019).

<sup>18</sup> *Kohler Co. v. Moen Inc.*, 12 F.3d 632, 642 (7th Cir. 1993).

<sup>19</sup> See, e.g., 73 Fed. Reg. 30,664, 30,675 (May 28, 2008) (Medicare Advantage and Part D plan context).

<sup>20</sup> *Whitman*, 531 U.S. at 468.

confidential commercial information would be protected from release under the Freedom of Information Act. 5 U.S.C. § 552(b)(4). CMS is attempting to avoid these constraints by threatening hospitals with penalties unless they disclose price information. But agencies may not do indirectly what they are not permitted to do directly. See *Cummings v. Missouri*, 71 U.S. 277, 278 (1867).

Finally, the regulatory history of the implementation of section 2718(e) also belies CMS's current interpretation of its authority to define standard charges to include negotiated charges. Prior rulemakings to implement section 2718(e) demonstrate that CMS is now overreaching in search for authority to require disclosure of payer-specific negotiated charges.

First, we note that, although section 2718(e) was enacted in 2010, CMS took no action to implement it until 2014, when the agency simply "reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation. At that time, we required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry."<sup>21</sup> Nothing in that rulemaking or any subsequent rulemaking until 2018 even remotely suggested that CMS believed it was authorized to define "standard charges" in a manner that would require hospitals to make public payer-specific charges. And for good reason: CMS did not interpret section 2718(e) to authorize the agency to require this disclosure.

Recently, CMS undertook rulemakings that discussed an expanded definition of standard charges. CMS first suggested it could require hospitals to disclose information beyond what was in the chargemaster in 2018.<sup>22</sup> Then, in 2018 and 2019, CMS and ONC issued requests for information (RFIs) in which they asked, among other things, how to define standard charge.<sup>23</sup> What is particularly noteworthy about the CMS RFIs is that they requested information on how to define standard charges in *non-hospital* settings without reference to *any* underlying statutory authority.<sup>24</sup> CMS's failure to cite any authority to require providers (other than hospitals, which are the only providers subject to section 2718(e)) and suppliers to make public their charge information suggests the agency was pursuing a policy objective without having identified a statutory basis for that policy. Such an approach is contrary to the role of agencies, which is to effectuate *Congress'* will. If an agency "believes the statute untoward in

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<sup>21</sup> 84 Fed. Reg. 39,175, 39,571 (Aug. 9, 2019).

<sup>22</sup> See 83 Fed. Reg. 41,144, 41,686 (Aug. 17, 2018).

<sup>23</sup> See, e.g., 83 Fed. Reg. 35,704, 36,009 (July 27, 2018); 83 Fed. Reg. 32,340 (July 12, 2018); 84 Fed. Reg. 7610 (Mar. 4, 2019).

<sup>24</sup> For example, in the 2019 home health prospective payment system proposed rule, CMS said: "We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting." 83 Fed. Reg. 32,340, 32,474 (July 12, 2018).

some respect, then ‘it should take its concern to Congress [;]’ . . . ‘[i]n the meantime it must obey [the statute] as written.’”<sup>25</sup>

ONC’s 2019 request for information is telling for other reasons. In it, ONC proposed to rely on a totally different section of the PHS Act from section 2718(e). ONC said that section 3022 of the PHS Act authorized it to require hospitals to disclose their negotiated prices.<sup>26</sup> In response to that proposal and as explained above, the AHA made the same point it makes here: Congress simply did not authorize ONC to require hospitals to disclose price information.<sup>27</sup> To date, ONC has not taken further action to require the disclosure of hospital price information. That may be because HHS decided instead to try to rely on the 2020 OPPS rulemaking for that purpose.

These recent efforts by CMS and ONC to reinterpret HHS’s authority to require hospitals to publicize payer-specific negotiated charges should be seen for what they are: Agencies searching for legal authority that Congress declined to delegate to them.

2. Standard charges for a hospital’s items and services do not include charges for physician services.

CMS said it would “include in our proposed definition of ‘items and services’ provided by *the hospital* the services furnished by *physicians and non-physician practitioners* who are employed by the hospital.”<sup>28</sup> As a textual matter, services furnished by *physicians and non-physician practitioners* simply are not items and services furnished by *the hospital*. Physicians furnish physicians’ services. Public payers like Medicare and Medicaid, as well as the vast majority of private payers, consider physicians’ services to be a distinct category of services.<sup>29</sup> And the distinction between hospital services and physician services is a long-established one. In the case of Medicare, it goes back to the program’s enactment,<sup>30</sup> and is reflected in numerous places in the law. For example, the Medicare statute specifically *excludes* physicians’ services from the definition of inpatient hospital services, which lists “items and services . . . furnished by the hospital . . . excluding, however[,] . . . medical or surgical services provided by a physician” or other practitioner.”<sup>31</sup> And, as reflective of the distinction between physicians’ services and items and services furnished by a hospital, only those

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<sup>25</sup> *Oceana, Inc. v. Locke*, 670 F.3d 1238, 1243 (D.C. Cir. 2011) (quoting *NRDC v. EPA*, 643 F.3d 311, 323 (D.C. Cir. 2011)).

<sup>26</sup> 84 Fed. Reg. 7,424, 7,513–14 (Mar. 4, 2019). See also 21st Century Cures Act, Pub. L. No. 114-255 § 4004, 130 Stat. 1033, 1176 (adding section 3022 of the PHS Act, as codified at 42 U.S.C. § 300jj-51).

<sup>27</sup> See AHA, Comment Letter Re: RIN 0955-AA01, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (June 3, 2019), available at <https://www.aha.org/system/files/media/file/2019/06/aha-let-onc-21st-century-cures-act-hit-proposed-rule-6-3-2019.pdf>.

<sup>28</sup> 84 Fed. Reg. 39,175, 39,577 (Aug. 9, 2019) (emphasis added).

<sup>29</sup> See, e.g., SSA § 1848(j)(3) (Medicare), § 1905(a)(5) (Medicaid).

<sup>30</sup> See [https://www.nasi.org/usr\\_doc/med\\_report\\_reflections.pdf](https://www.nasi.org/usr_doc/med_report_reflections.pdf).

<sup>31</sup> See SSA 1861(b).

Medicare beneficiaries enrolled in Medicare Part B are entitled to have Medicare pay for physicians' services.<sup>32</sup>

In other words, when Congress adopted the standard charges requirement in the ACA, it was aware of the distinction between hospital services and physician services and consciously chose to limit the scope of the standard charges provision to "hospital" services — which has long been understood to exclude "physician" (and non-physician practitioner) services. Cf. [Garcia v. Dep't of Homeland Sec., 437 F.3d 1322, 1336 \(Fed.Cir.2006\)](#) ("Congress is presumed to enact legislation with knowledge of the law and a newly-enacted statute is presumed to be harmonious with existing law."). If Congress had intended the standard charges provision to require public reporting of physician services, Congress surely would have said so. "[W]here Congress knows how to say something but chooses not to, its silence is controlling," *In Re Griffith*, F. 3d 1389, 1394 (11th Cir. 2000).

Moreover, contrary to CMS's view, the right of a hospital (or other entity) to bill and be paid for services furnished by employed physicians does not transform those physicians' services into items and services furnished by the hospital.<sup>33</sup> Rather, where a hospital bills and is paid for physician services, the physicians simply have reassigned their benefits to their employer. In Medicare, that occurs under a provision of the statute that specifically authorizes reassignment of benefits.<sup>34</sup> If physicians' services were, in fact, items and services furnished by the hospital, no reassignment would be needed. Based on these legal distinctions, as well as the operational problems discussed below, CMS should decline to adopt its proposal to include the services of physicians and other practitioners in the items and services for which hospitals will be required to disclose their standard charges.

C. Requiring hospitals to make public more than one list is an additional violation of the plain language of the statute.

Section 2718(e) authorizes *only one* list of standard charges — "a list" — whereas CMS would require hospitals to make public three lists: (1) a list of gross charges for inpatient and outpatient items and services; (2) a list of payer-specific negotiated charges for those same services; and (3) a list of payer-specific negotiated charges for 300 shoppable "service packages."

CMS says it is requiring "a list," but then describes gross charges and payer-specific negotiated rates as "data elements" in that list. CMS cannot circumvent the strictures of the statute, which uses the words "a list," to mandate multiple lists by re-characterizing

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<sup>32</sup> See SSA § 1832(a)(2)(B).

<sup>33</sup> Nor would the inclusion of employed physicians' charges on a hospital's chargemaster make the physicians' services into items and services *furnished by* the hospital.

<sup>34</sup> See SSA 1842(b)(6).

the separate lists as “data elements” in a single list of standard charges. The statute requires hospitals to make public only one list, not three.<sup>35</sup>

II. Requiring public disclosure of payer-specific negotiated charges would violate the First Amendment.

CMS’s proposal would violate the First Amendment by compelling the public disclosure of individual charges privately negotiated between hospitals and health plans. Government regulation of non-misleading commercial speech is unlawful unless it “directly advances” a “substantial” governmental interest, and is no “more extensive than is necessary to serve that interest.”<sup>36</sup> The proposed rule fails that test here.

A. The proposed rule does not directly advance a substantial governmental interest.

First, the agency’s proposal to mandate disclosure of the charges privately negotiated between hospitals and health plans does not directly advance a substantial governmental interest. CMS’s stated interest in controlling costs and putting *consumers* “at the center of their health care” is unlikely to be served by the mandated disclosure of charges privately negotiated between hospitals and *health plans*.

As the FTC has recognized: “To be most meaningful, price information should reflect an individual consumer’s desired health care coverage—including specific out-of-pocket expenditures for specific procedures and services—so that the consumer can make informed decisions when selecting a provider or choosing among treatment options.”<sup>37</sup> And the agency’s own research makes clear that when it comes to price information, patients are interested in their *own* out-of-pocket costs — not their health plan’s costs. As CMS itself admits: “consumers of health care services simply want to know where they can get a needed health care service and what that service will cost them *out of-pocket*.”<sup>38</sup> For this reason, the link between the mandated disclosure of health plan-negotiated charges and the desired impact on consumers is both “tenuous” and “highly speculative.”<sup>39</sup>

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<sup>35</sup> See *U.S. v. Hayes*, 555 U.S. 415, 421 & n.4 (2009) (Congress’s use of the singular shows that Congress “intended to describe only one required element. . . . Had Congress meant to [allow for an additional factor also to be a required element] it likely would have used the plural.”).

<sup>36</sup> *Central Hudson Gas & Electric Corp. v. Public Service Comm’n of New York*, 447 U.S. 557, 566 (1980). The agency has failed to identify a sufficient predicate to justify the application of *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985) to the facts presented here. But the regulation fails under either test. Even under *Zauderer*, a disclosure requirement cannot be “unjustified or unduly burdensome.” *Id.* at 651.

<sup>37</sup> FTC letter for members of the Minnesota House of Representatives (June 29, 2015).

<sup>38</sup> *Id.* (emphasis added).

<sup>39</sup> *Central Hudson*, 447 U.S. at 569. See also *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (holding unlicensed clinic notification requirement unlawful because the government had not shown that it was remedying a harm that was “more than purely hypothetical”).

In fact, the disclosure of negotiated charges between hospitals and health plans is more likely to *confuse* patients than to ameliorate any existing lack of information. Patients would reasonably expect that information posted on hospital websites for the stated purpose of allowing them to compare costs would allow them to do precisely that — compare their out-of-pocket costs. But the information that would be compelled by the proposed rule relates solely to charges to be paid by health plans, and would require patients to perform several further calculations to determine their out-of-pocket costs, such as what their co-pay obligations are and where they are in their deductibles. As a result, patients are more likely to be misled than edified by the information CMS would compel hospitals to disclose.

Finally, CMS has asserted that the proposed rule is designed to take an “important step toward putting consumers at the center of their health care.”<sup>40</sup> But the agency’s repeated admissions that the proposed disclosures are merely a “first step” or a “step towards” the rule’s stated goals make clear that the proposed rule does not “directly” and “materially” serve the stated interest.<sup>41</sup> As a result, it would violate the First Amendment.

B. The mandated disclosure is not narrowly tailored to the stated government interest.

Even if this first hurdle could be overcome, CMS’s proposal nonetheless would be unlawful because the mandated disclosure is much more extensive than necessary to serve the proffered interest. Because hospitals rely heavily on the confidentiality of health plan-negotiated charges to permit them to negotiate arm’s-length charges with other health plans, disclosure of charges negotiated with individual health plans would unduly burden hospitals’ ability to enter into competitive contracts and goes well beyond the level of regulation necessary to promote the stated government interest. In comment letters on a similar government proposal earlier this year, a number of insurers agreed with our position and expressed concern that the rule would have anti-competitive effects.

In addition, the charges negotiated between hospitals and health plans are confidential trade secrets.<sup>42</sup> As such, requiring their public disclosure would infringe upon intellectual property rights recognized by Congress and individual states.<sup>43</sup> A trade secret is generally defined as “any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over

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<sup>40</sup> 84 Fed. Reg. 39398, 39,574 (Aug. 9, 2019).

<sup>41</sup> See *id.* at 39,574, 39,585, 39,611.

<sup>42</sup> See *West Penn Allegheny Health Sys., Inc. v. UPMC*, 2013 WL 121441532 (W.D. Pa. Sept. 16, 2013) (“[i]nformation regarding pricing and rates constitutes trade secret information”).

<sup>43</sup> 18 U.S.C. § 1836.

competitors who do not know or use it.”<sup>44</sup> The factors considered in evaluating whether a trade secret exists typically include:

(1) the extent to which the information is known outside of [the] business; (2) the extent to which it is known by employees and others involved in [the] business; (3) the extent of measures taken by [the business] to guard the secrecy of the information; (4) the value of the information to [the business] and [its] competitors; (5) the amount of effort or money expended by [the business] in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.<sup>45</sup>

The charges negotiated between hospitals and health plans are kept strictly confidential.<sup>46</sup> Like any privately negotiated price in a market where multiple parties are negotiating on multiple platforms, the negotiated charges between a hospital and any particular health plan derive their value from not being publicly known. If hospitals are required to disclose their negotiated charges with health plans publicly, it would be virtually impossible for hospitals and health plans to negotiate competitive pricing in the future at arm’s length. That is why courts regularly shield hospital-health plan pricing agreements from discovery and disclosure in litigation. *See, e.g., Medical Center at Elizabeth Place, LLC v. Premier Health Partners*, 294 F.R.D. 87 (S.D. Ohio 2013) (shielding pricing agreements between health plan and hospitals from discovery on basis that they were highly confidential); *Ball Mem. Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1346 (7th Cir. 1986) (entering protective order and noting that pricing negotiated between health plans and hospitals was “unquestionably sensitive trade secrets” of the health plans because it could be used against the health plans “in the next round of negotiations”). The same holds true here, and then some; if pricing agreements are shielded from disclosure even when they are directly relevant to specific litigation, surely they are protected when they are to be disclosed *en masse* to the public. The proposed rule therefore goes much too far in requiring their public disclosure — both beyond the scope of regulation necessary to achieve the rule’s stated aims, and into trade secret territory expressly protected by Congress and individual states.

For all the above reasons, mandating the public disclosure of trade secrets protected under both federal and state law would result in extreme harm to hospitals and health plans alike. The agency has failed to demonstrate that the proposed regulation is

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<sup>44</sup> Restatement of Torts sec. 757, Comment B; *see also* 18 U.S.C. § 1839(3) (defining trade secret as “all forms and types of financial, business, scientific, technical, economic, or engineering information . . . , if (A) the owner thereof has taken reasonable measures to keep such information secret; and (b) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.”).

<sup>45</sup> *Id.*

<sup>46</sup> *See, e.g., Medical Center at Elizabeth Place, LLC v. Premier Health Partners*, 294 F.R.D. 87, 94 (S.D. Ohio 2013).



narrowly tailored or that its interests “cannot be protected adequately by more limited regulation of . . . commercial expression.”<sup>47</sup>

III. CMS lacks authority to impose penalties on hospitals that fail to provide the standard charge information the proposed rule would require.

CMS relies on section 2718(b)(3) of the ACA for its authority to enforce the requirement that hospitals make their standard charges public. That reliance is completely misplaced. CMS’s enforcement authority is limited to section 2718(a) and (b)(1). To conclude otherwise is contrary to Congress’s clear intent and flies in the face of the enactment history and structure of section 2718. It also is inconsistent with HHS’s prior view of the ambit of section 2718(b)(3).

Section 2718 contains several disparate provisions under the section heading “Bringing down the cost of health care coverage.”

- Subsection (a) applies to reporting requirements (for what is frequently termed medical-loss ratio (MLR) information) by health plans on the health exchanges.
- Subsection (b) requires health plans on the health exchanges that fail to meet MLR requirements to provide premium rebates to enrollees and requires states to take certain steps to further the policy objectives of the MLR requirements.
- Subsection (c) requires the National Association of Insurance Commissioners (NAIC) to establish definitions and methodologies needed for health plans to comply with subsections (a) and (b).
- Subsection (d) gives HHS authority to adjust the rates of health plans in the exchanges.
- Subsection (e) requires hospitals to make public their standard charges.

Until CMS published the 2020 OPPTS proposed rule, the agency never said that it had authority to enforce through penalties the requirement in section 2718(e) that hospitals make public their standard charges. We believe there is good reason for that: CMS knew that section 2718(b)(3) does not authorize enforcement of section 2718(e). Indeed, HHS implicitly acknowledged the narrow scope of section 2718(b)(3) when it implemented the MLR requirements in 2010 and said that the regulations promulgated “implement enforcement authority in section 278(b)(3) and provide for enforcement of the reporting obligations set forth in *section 2718(a) and rebate requirements in section 2718(b).*”<sup>48</sup> HHS did not even suggest that section 2718(b)(3) might apply to section 2718(e). Rather, HHS correctly recognized that section 2718(b)(3) authorizes enforcement of the requirements in only subsection (a) and paragraph (1) of subsection (b) of section 2718. That is, the MLR rebate requirements applicable to health plans.

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<sup>47</sup> *Central Hudson*, 447 U.S. at 570.

<sup>48</sup> 75 Fed. Reg. 74,864, 74,889 (Dec. 1, 2010).

## A. History of the statutory enactment

The history of the ACA's enactment makes plain that the enforcement provision at section 2718(b)(3) is intended to apply only to the MLR provisions at section 2718(a) and (b).

Section 2718(b)(3) states: "The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties." CMS presumably reads the reference to "this section" to include section 2718(e); but that reading cannot be squared with the actual history of the enactment of section 2718. That enactment history shows that the enforcement provision is intended to apply only as to the MLR provisions, and that the reference to "section" is a scrivener's error that arose when Congress consolidated a stand-alone MLR provision and various other stand-alone provisions into section 2718 of the ACA.

The MLR requirements originally appeared as stand-alone Senate and House bills on September 30, 2009.<sup>49</sup> Those bills included an enforcement provision with language identical to that currently in section 2718(b)(3). Neither bill included a *hospital standard charges provision* or NAIC provision.<sup>50</sup> In other words, the enforcement provision applied exclusively to the MLR requirements.

The standard hospital charges provision also was initially included in its own distinct provision of the Senate Finance Committee bill that was the precursor to the ACA.<sup>51</sup> That language, as revised slightly via a floor manager amendment on Nov. 19, 2009,<sup>52</sup> was ultimately enacted in the ACA. It is particularly noteworthy that *neither section 1502 of the Senate Finance Committee bill nor the floor manager amendment included any type of enforcement provision — much less a penalty provision — for failure to disclose hospital standard charges.*

The requirement in section 2718(c) that the NAIC establish definitions and methodologies to implement the MLR provisions at section 2718(a) and (b) was first included in a December 4, 2009 floor amendment by Senator Franken.<sup>53</sup> Prior to that date, under the floor manager amendment, *the Secretary was to establish the*

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<sup>49</sup> Fairness in Health Insurance Act, S. 1730, 111th Cong. § 2 (2009), available at <https://www.congress.gov/bill/111th-congress/senate-bill/1730/text?q=%7B%22search%22%3A%5B%22s1730%22%5D%7D&r=6&s=4>, and its companion bill H.R. 3681, 111th Cong. § 2 (2009), available at <https://www.congress.gov/bill/111th-congress/house-bill/3681>.

<sup>50</sup> See S. 1730, 111th Cong. § 2 (Sept. 30, 2009). Similarly, neither bill included an obligation for states to further the goals of the MLR provisions, which was added in a November 19, 2009 Senate floor manager amendment. S. Amend. No. 2786, 111th Cong. § 1 (Nov. 19, 2009), available at <https://www.congress.gov/111/bills/hr3590/BILLS-111hr3590as.pdf>.

<sup>51</sup> S. 1796, 111th Cong. § 1502 (Oct. 19, 2009).

<sup>52</sup> S. Amend. No. 2786, 111th Cong. § 1 (Nov. 19, 2009), available at <https://www.congress.gov/111/bills/hr3590/BILLS-111hr3590as.pdf>.

<sup>53</sup> 155 Cong. Rec. at S12429 (Dec. 4, 2009) (floor amendment).

definitions and methodologies *in consultation with the NAIC*.<sup>54</sup> It is not clear why the responsibility to establish MLR definitions and methodologies shifted from the Secretary to the NAIC between the November 19 and December 4, 2009.

On Dec. 4, 2009, the various stand-alone provisions were merged into section 2718 of the ACA: The MLR requirements on health plans (and enforcement of them) and a version of the requirement for establishing MLR definitions and methodologies were consolidated with the standard hospital charges provision in a Senate Amendment to the bill that became the ACA.<sup>55</sup> With some (non-relevant) further amendment, the Dec. 4, 2009 version of section 2718 later became the Senate version of the ACA that was adopted on December 24, 2009.<sup>56</sup>

B. Use of the word “section” in section 2718(b)(3) was a scrivener’s error.

When the MLR provision was consolidated with the various other disparate provisions into section 2718 of the ACA, it is clear that Congress was trying to simplify the statute by placing a series of free-standing provisions under a single catch-all section. Yet when it did so, “Congress made a technical mistake” by leaving “unmodified the cross-referencing language” in the MLR enforcement provision.<sup>57</sup> Instead, Congress should have updated the cross-reference so that the enforcement provision would apply as intended (and as it originally appeared in the stand-alone version of the provision). In other words, the history of the enactment of the enforcement provision at section 2718(b)(3) shows that it was plainly drafted to allow HHS to enforce the *MLR requirements* on health plans in section 2718(a) and (b). Section 2718(b)(3)’s use of the term “section” rather than “subsection” is what courts consider a scrivener’s error.<sup>58</sup>

Where the “history of [a] provision makes . . . clear” that Congress plainly intended a particular result, courts can “escape” errors in Congress’s wording or language “by

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<sup>54</sup> S. Amend. No. 2786, 111th Cong. § 1 (Nov. 19, 2009), *available at* <https://www.congress.gov/111/bills/hr3590/BILLS-111hr3590as.pdf>. (“(d) DEFINITIONS.—Not later than December 31, 2010, the Secretary, in consultation with the National Association of Insurance Commissioners, shall establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities.”)

<sup>55</sup> Authority for HHS to adjust health plans rates was subsequently added at section 2718(d) as part of an amendment that was proposed on December 19, 2009 and agreed to by the Senate on December 22, 2009. See S. Amend. No. 3276, 111th Cong. (Dec. 19, 2009), *available at* <https://www.congress.gov/crec/2009/12/19/CREC-2009-12-19-pt1-PgS13490-2.pdf>.

<sup>56</sup> See S. Amend. No. 3298, 111th Cong. (Dec. 24, 2009), *available at* <https://www.congress.gov/111/bills/hr3590/BILLS-111hr3590eas.pdf>. See also *All Information (Except Text) for H.R. 3590 – Patient Protection and Affordable Care Act*, Congress.gov, <https://www.congress.gov/bill/111th-congress/house-bill/3590/all-info> (last visited Sept. 2, 2019) (stating Senate Amendment No. 3298 was passed by the Senate on December 24, 2009).

<sup>57</sup> See *Dir., Office of Workers’ Comp. Programs, U. S. Dep’t of Labor v. Peabody Coal Co.*, 554 F.2d 310, 331 (7th Cir. 1977).

<sup>58</sup> See, e.g., *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50 (2004) (Stevens, J., concurring); *Barnette v. Brook Road, Inc.*, 429 F. Supp. 2d 741 (E.D. Va. 2006); *Moore v. D.C.*, 907 F.2d 165 (D.C. Cir. 1990).

using common sense” to effectuate the clear intent of Congress.<sup>59</sup> “[A] busy Congress is fully capable of enacting a scrivener’s error into law,”<sup>60</sup> and the Supreme Court has emphasized the need for a “‘holistic’” approach to statutory construction to avoid effectuating results inconsistent with Congress’s intent.<sup>61</sup> And the Congress that enacted the ACA most definitely was busy: “The ACA’s legislative process was extremely intense, lengthy, and complex.”<sup>62</sup> As a consequence, “[t]he Affordable Care Act contains more than a few examples of inartful drafting,” which is a byproduct of the “unfortunate reality” that “Congress wrote key parts of the Act behind closed doors, rather than through ‘the traditional legislative process’ . . . [a]nd Congress passed much of the Act using a complicated budgetary procedure known as ‘reconciliation,’ which limited opportunities for debate and amendment.”<sup>63</sup> As a result, there is a special need for the “words of [the] statute [to] be read in their context and with a view to their place in the overall statutory scheme.”<sup>64</sup>

Further, where a scrivener’s error produces absurd results, there is a double reason to reject an “unambiguous” reading of a statute. That is the case here. If section 2718(b)(3) applies to all of section 2718 rather than just the MLR provisions in section 2718(a) and (b), HHS would be able to penalize states and the NAIC. CMS does not suggest it can take action against either. Indeed, following the ACA’s enactment, the Secretary of HHS made clear that she saw the Department as a partner with — rather than a regulator of — the NAIC *in implementing section 2718*.<sup>65</sup> Moreover, HHS has never taken enforcement action against the NAIC. That is likely because nowhere in the ACA (or otherwise) does HHS have authority over the NAIC. And there is no reason to think that Congress intended HHS to be able to enforce against the NAIC in only this circumstance. Thus, interpreting section 2718(b)(3) as CMS does leads to an absurd result: That provision cannot be read to authorize the agency to impose penalties on hospitals for failing to make public payer-specific negotiated rates.

Operational Challenges of CMS Proposal. In addition to our legal concerns, the AHA has significant operational concerns with this proposal. The proposal, if finalized, would impose an excessive burden on hospitals and health systems — far exceeding CMS’s estimate of 12 hours. To prepare for the January 2019 deadline to post all standard charges in a machine-readable format, hospitals and health systems often spent more than 100 hours manually creating the files and updating their websites. The file CMS would require under the proposed rule would be exponentially larger, including not only the items and services reflected in the chargemaster (often tens of thousands of rows but in some instances well over 100,000) but also rows reflecting the myriad different

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<sup>59</sup> *Koons Buick Pontiac GMC, Inc.*, 543 U.S. at 65 (Stevens, J., concurring).

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 60 (maj. op.).

<sup>62</sup> Abbe R. Gluck, *Imperfect Statutes, Imperfect Courts: Understanding Congress’s Plan in the Era of Unorthodox Lawmaking*, 129 Harv. L. Review. 62, 67 (2015).

<sup>63</sup> *King v. Burwell*, 135 S. Ct. 2480, 2492 (2015).

<sup>64</sup> *Id.*

<sup>65</sup> See Letter from Kathleen Sebelius to NAIC (April 12, 2010) in which she wrote: “I am writing this letter to request NAIC’s assistance relating to implementation of the provisions in Section 2718 of the PHS Act.”

ways individual health plan issuers define payments (e.g., per diems, diagnosis-related groups (DRGs), and other episode and value-based payments). This could introduce thousands or even hundreds of thousands of additional rows to the required spreadsheet.

CMS's proposal also would require hundreds to thousands of columns. In addition to descriptions, codes, and gross charges, the spreadsheet would need to include separate columns for each health plan issuer contract. Many hospitals and health systems have over 100 contracts with different health plan issuers, often with multiple contracted rates depending on the type of health plan (e.g., Medicare Advantage, individual market health maintenance organization (HMO), individual market preferred provider organization (PPO), each self-insured plan). Hospitals and health systems report that a file of this size could easily crash most standard computer systems, and some members worry about the ability of their websites to function at all with such a large file.

Even if patients could navigate such a large file to find the negotiated charges corresponding to their health plan issuer and health plan type, they would still be many steps away from deriving an estimate of their out-of-pocket costs. A patient's out-of-pocket costs depends on a number of factors, including their health plan product's benefit design and where the patient is relative to meeting her deductible or maximum out-of-pocket spending limit. At best, the charge that the health plan issuer has negotiated for an item or service is only one piece of determining a patient's expected out-of-pocket cost. For example, for a coinsurance benefit, a patient's expected out-of-pocket cost would be determined by the coinsurance percentage, the negotiated charge, where the individual is within her deductible, and where the individual is in relation to the maximum out-of-pocket cost limit.

An analysis of the individual market in Federally-Facilitated Marketplace states found that hospitals had, on average, between two and three health plan issuers in their markets. These issuers, on average, offered 34 different plans with an average of 142 unique benefit design variations. As mentioned above, hospitals and health systems often have different contracted rates with issuers for different types of products (e.g., one rate for HMO plans, another rate for PPO plans). Therefore, even for the small sliver of the market captured through the individual market, hospitals can have multiple negotiated charges.

And while patients in the individual market have access to an average of 142 benefit designs that are differentiated, in part, by variations in cost-sharing requirements, in several markets, the number of unique benefit designs ranges from 501 to more than 1,000. Looking more holistically, the hundreds of contracts that many hospitals maintain could easily translate to thousands of benefit designs. Even if the negotiated charges for all of those plans were the same (which they most often would not be), knowing those charges would not help individuals understand what their own out-of-pocket costs would be. Where individual patients are in reaching their deductible and total out-of-pocket

spending impact what they ultimately pay. For many services, patients need to pay the full amount negotiated for a service until they have spent an amount equal to their deductible. Upon reaching their deductible, patients often still have some form of cost-sharing, such as a copay or coinsurance. However, once patients reach an out-of-pocket maximum, they no longer are subject to any type of cost-sharing. All of these specifics (e.g., the deductible, out-of-pocket maximum amounts, copay and coinsurance details) make up a health plan product's benefit design. Without benefit design details and information on an individual's out-of-pocket spending throughout the year, the negotiated charge will not enable patients to determine what they may owe.

An example of how patients' out-of-pocket costs can vary based on their benefit structure and health spending throughout the year follows. This example looks at one health plan issuer's different individual market health plan products in a single rating area, using the publicly available Plan Attribute file.<sup>66</sup> This analysis looks at the varying benefits for a service with an assumed (for simplicity's sake) negotiated charge of \$500.

Health Plan Issuer 1					
Health Plan Product	Health Plan Benefit Design		Examples of Potential Patient Cost-sharing		
	Deductible <sup>67</sup>	Benefit <sup>68</sup>	Pre-Deductible	Post-Deductible	\$3K Into Deductible
Product 1	\$7,900	\$0	\$500	\$0	\$500
Product 2	\$7,900	\$0	\$500	\$0	\$500
Product 3	\$6,650	\$0	\$500	\$0	\$500
Product 4	\$5,150	35%	\$500	\$175	\$500
Product 5	\$5,300	25%	\$500	\$125	\$500
Product 6	\$5,150	35%	\$500	\$175	\$500
Product 7	\$5,300	25%	\$500	\$125	\$500
Product 8	\$200	35%	\$305	\$175	\$175
Product 9	\$200	25%	\$275	\$125	\$125
Product 10	\$1,000	25%	\$500	\$125	\$125
Product 11	\$3,500	35%	\$500	\$175	\$500
Product 12	\$800	35%	\$500	\$175	\$175
Product 13	\$3,300	25%	\$500	\$125	\$350

<sup>66</sup> Plan Attributes PUF (updated July 25, 2019), select data benefit design information for one health plan issuer in Colorado's Rating Area 1 (Boulder); data available at:

<https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.html>;

<sup>67</sup> Reflects individual deductible.

<sup>68</sup> In-network (tier 1) imaging benefit; \$0 benefits indicate no cost-sharing after the deductible; percentage benefits indicate co-insurance after the deductible; dollar value benefits above \$0 indicate a co-pay after the deductible.

<b>Product 14</b>	\$2,600	\$500	\$500	\$500	\$500
<b>Product 15</b>	\$2,000	\$250	\$500	\$250	\$250
<b>Product 16</b>	\$200	\$200	\$400	\$200	\$200
<b>Product 17</b>	\$700	\$200	\$500	\$200	\$200
<b>Product 18</b>	\$2,500	\$500	\$500	\$500	\$500
<b>Product 19</b>	\$200	\$200	\$400	\$200	\$200
<b>Product 20</b>	\$1,400	\$250	\$500	\$250	\$250
<b>Product 21</b>	\$2,000	\$250	\$500	\$250	\$250
<b>Product 22</b>	\$2,600	\$500	\$500	\$500	\$500
<b>Product 23</b>	\$5,800	\$500	\$500	\$500	\$500
<b>Product 24</b>	\$5,000	\$250	\$500	\$250	\$500
<b>Product 25</b>	\$800	\$200	\$500	\$200	\$200
<b>Product 26</b>	\$2,000	\$250	\$500	\$250	\$250

Even if such a file were to be useful, which we do not believe would be the case based on the arguments above, building such a file to meet CMS’s specifications may not even be possible. Often times, health plan issuer/provider contracts will start with a basic discount off of charges. However, a number of different rules — documented in many dozens of pages of text in the contract — are applied to claims that change the actual reimbursement rate. A common contractual adjustment that would preclude a provider from telling a given patient what the negotiated charge is for a particular service is issuers’ use of proprietary algorithms to bundle services. Providers do not always know how billed services will be bundled and paid on a given claim until the claim has been adjudicated. Many contracts also include protection clauses, such as stop loss clauses or not to exceed clauses, which could change the final rate paid for a service.

In addition, once created, the file will almost immediately become outdated as contracts are regularly updated more frequently than annually but at different intervals. Some charges, especially those for drugs, can change daily based on changes in acquisition costs. To create and accurately maintain this file, hospitals and health systems would likely need to dedicate at least one full-time equivalent, with some larger members suggesting that an entire new department may be needed. This is significantly more time and resource intensity than CMS’s estimate of four hours.

Similarly, CMS grossly underestimates the time it would take for hospitals to identify 300 shoppable services and their corresponding customary ancillary services, and create an easily searchable, consumer-friendly website. It would take significant staffing resources to identify “service packages” for each of the 300 shoppable services. In some instances, this would once again be impossible as not all facilities, such as rehabilitation hospitals, even provide 300 shoppable services.

Hospitals and health systems also would need considerable time and resources to build a web-based tool to display this information, as well as determine an appropriate format

for a paper-based version. Most hospitals and health systems would need to hire technology vendors to build the online tool and potentially help with identifying and bundling the services. Once again, new files would need to be created to feed into the web-based tool — something that would be a manual process — as no existing systems can easily identify and accurately format this information. In addition to creating the file, staff would need to regularly update the data and perform quality reviews. Hospitals have reported that developing and implementing an out-of-pocket cost estimator tool can take well over a year, even when working with vendors already in the market, and these tools generally start with only a few dozen services. For example, a division of a large health system launched their tool over two years ago. While growing, the tool currently can provide out-of-pocket cost estimates for about 200 common procedures.

Finally, aspects of this proposal refute the very nature of shoppability. Specifically, the approach outlined by CMS would not allow for meaningful comparisons across hospitals. Each hospital is going to develop “service packages” based on their unique mix of auxiliary services. Using this tool, patients would not be able to easily compare the rates at one hospital versus another — a stated goal of this policy. And, to reiterate, patients still would know little to nothing about their potential out-of-pocket costs.

In summary, the proposed approach would not give patients the information they need to make informed health decisions while introducing significant additional burden and resource requirements into the health care system. For all of this cost and effort, we anticipate that almost no patients would use the tool and instead they will continue to contact hospitals and health systems directly for more accurate out-of-pocket cost estimates.

Advancing Price Transparency: Focus on Out-of-Pocket Cost Estimates. As affirmed throughout our comments above, the cost information that patients actually need to make informed decisions about their care is their potential out-of-pocket cost obligation. Hospitals and health systems are committed to facilitating patient access to this type of information and would appreciate the opportunity to work with patients, CMS and other stakeholders on these efforts. Our members have a long history of working with patients to provide estimates of out-of-pocket costs, traditionally through the use of financial counselors and other patient support staff. Technological advances have enabled some members to supplement these resources with online out-of-pocket cost estimator tools, with many others expressing interest in developing these types of tools in the near future.

Hospitals and health systems focus on out-of-pocket cost estimates because this is the information that patients ask for and say they need. For example, since January 2019, one health system reports receiving more than 20,000 patient inquiries related to out-of-pocket costs. In comparison, the system only has received one patient inquiry related to the standard charge file posted on its website. This is consistent with what we’ve heard from hospitals and health systems across the country.



The research — and other government agencies — support the focus on out-of-pocket costs. According to the Commonwealth Fund, “price transparency absent corresponding quality and out-of-pocket-cost data may lead to poor health care choices and higher costs, without improvements in the care provided.”<sup>69</sup>

As discussed above, because CMS has no authority to mandate the disclosure of negotiated prices, we urge CMS to focus on the role it could play in convening stakeholders to identify best practices for providing patients with out-of-pocket cost estimates, recommend parameters for cost-estimator tools, and develop solutions to common technical barriers.

To that end, CMS could facilitate greater adoption of out-of-pocket cost estimator tools by lowering the barriers to entry. Cost estimator tools are resource intensive to stand up and maintain. Our members report spending years developing and honing these tools. They typically hire one or more vendors to build the tool and/or provide data management support, as well as dedicate significant staff resources to organize the back-end data, provide quality reviews and updates, work with health plans on obtaining benefit information, and work with the vendors on deployment and updates.

CMS could convene key stakeholders in a learning collaborative — potentially through a Center for Medicare & Medicaid Innovation demonstration project — to develop standards for implementation, easing some of the burden associated with building these types of tools from scratch each time. Providers, health plans, and technology vendors could work with CMS to identify potential standards and technical specifications for estimator tools, which could be shared for adoption across the field.

## **PROPOSED FULL PHASE-IN OF SITE-NEUTRAL PAYMENT CUT FOR HOSPITAL OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS**

In the CY 2019 OPSS proposed rule, CMS described “unnecessary” increases in the volume of hospital outpatient clinic visits in excepted off-campus provider-based departments (PBDs) and, citing its authority under section 1833(t)(2)(F) of the Social Security Act (SSA), proposed to pay for clinic visits furnished in excepted off-campus PBDs at an amount that equals 40% of the OPSS rate. CMS further proposed to implement this proposal in a non-budget neutral manner, which the agency estimated would result in a CY 2019 reduction of \$760 million in hospital payment under the OPSS.

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<sup>69</sup> Gustafsson, L. and Bishop, S., “Hospital Price Transparency: Making It Useful for Patients.” The Commonwealth Fund. February 12, 2019. Available at: <https://www.commonwealthfund.org/blog/2019/hospital-price-transparency-making-it-useful-patients>.

Many commenters questioned the assumptions underlying the agency's conclusions – especially the conclusion that hospital outpatient department (HOPD) services had increased unnecessarily. Numerous commenters also questioned CMS's legal authority to cut payments to excepted off-campus PBDs and to make those payment cuts in a non-budget neutral manner. Indeed, the AHA's comments on the clinic visit payment cut proposal spanned 15 pages and took issue with a host of CMS's factual assumptions and legal conclusions. Among other things, the AHA said that CMS had no basis for its assertion that HOPD services had increased unnecessarily; CMS lacks statutory authority to reduce payments to excepted PBDs; the proposal is arbitrary and capricious; and implementing the clinic visit policy in a non-budget neutral manner is contrary to the plain language of the statute. The AHA further urged CMS to withdraw the proposal.

Despite the many concerns and objections raised by the AHA and other commenters, CMS's CY 2019 OPPS final rule adopted the proposal to cut payments to excepted PBDs and make the cuts in a non-budget neutral manner. In a change from the proposed rule, however, the agency elected to phase in the payment reduction over two years – 50% in 2019 and the remaining 50% in 2020.

The AHA, three of its member hospitals and the Association of American Medical Colleges (AAMC) filed suit in January 2019 to challenge the new clinic visit payment policy. They alleged that hospitals with excepted off-campus PBDs faced imminent injury as a result of CMS's unlawful decision to reduce clinic visit payment rates and to do so in a non-budget neutral manner.

In the CY 2020 OPPS proposed rule, CMS refers readers to the CY 2019 OPPS final rule for “a detailed discussion of the background, legislative provisions, and the changes in payment policies we developed to address increases in the volume of covered OPD services.”<sup>70</sup> The agency then explains that, through the CY 2020 OPPS rule, it is “completing the phase-in of the reduction in payment for the clinic visit services...furnished in expected [sic] off-campus provider-based departments as a method to control unnecessary [sic] increases in the volume of this service.”<sup>71</sup>

The AHA continues to believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus PBDs in 2019 is unlawful and is causing undue harm to hospitals for the reasons explained in its lawsuit challenging the 2019 OPPS final rule. Among other things, Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare.<sup>72</sup> Changes to payments that target only specific items or services must be budget neutral.<sup>73</sup> In addition, by subjecting excepted and nonexcepted PBDs to the exact same

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<sup>70</sup> 84 Fed. Reg. 39,398, 39,528 (Aug. 9, 2019).

<sup>71</sup> Id.

<sup>72</sup> SSA §1833(t)(9)(A).

<sup>73</sup> Id. § 1833(t)(9)(B).

payment system and payment rate, the agency has inappropriately abolished the statutory distinction between those two entities.

**The court recently found that the agency exceeded its statutory authority when it cut the payment rate for clinic services at excepted off-campus provider based clinics.**

**We, therefore, urge CMS to:**

**(1) Immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts;**

**(2) Promptly repay hospitals the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates; and**

**(3) Abandon its proposed second phase of the payment cut in 2020. Should the agency move forward with the second phase of the cut, it will cause additional harm to many hospitals and the AHA intends to pursue its legal remedies.**

The Growth in Outpatient Volume and Expenditures is not “Unnecessary”. In the CY 2020 proposed rule, CMS proposes to implement the full 60% 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. 19, 2019 meeting of CMS’s Advisory Panel on Hospital Outpatient Payment, members expressed concern that CMS had not followed through on its 2018 recommendation that the agency *not implement* the proposal for reduction in payment for outpatient clinic visits and instead study the matter to better understand the reasons for increased utilization of outpatient services. **Indicating their continued concern about the lack of evidence to support CMS’s clinic visit payment reduction and the policies’ possible impacts on access to care, the Panel voted unanimously to recommend that CMS freeze the payment policy for off-campus clinic visits at CY**

**2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased.**

**Blaming increases in OPSS expenditures on the “unnecessary” shifting of services from physician offices to PBDs in response to payment differentials ignores 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 3% of their Medicare inpatient 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 fiscal year (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](#) conducted at the time this policy was revised demonstrated that it 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. The Medicare Payment and Advisory Commission (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.<sup>74</sup> In its March 2019 report, MedPAC noted, “Shift of some services from the inpatient to the outpatient setting has increased OPSS spending. Growth in relatively complex services – such as spinal surgeries; endovascular procedures; and removal, replacement, or insertion of defibrillator systems or pulse generators – suggests that some of the growth in OPSS spending is from services migrating from the inpatient to the outpatient setting.”<sup>75</sup> 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 large increase in OPSS spending from 2013 to 2014 (a 12.8% increase).<sup>76</sup> 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 28 procedures from this list, including, notably, total knee arthroplasty (TKA). This trend would accelerate if the agency finalizes its proposal to remove total hip arthroplasty (THA) from the IPO list in 2020. The shifting of Medicare procedures from the inpatient to the outpatient setting is an intended result of this policy and is another driver of OPSS volume and expenditures.

*Factors Outside of 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 hospitals’ control. We highlight a few below. Again, by definition, increases in volume and expenditures resulting from these trends

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<sup>74</sup> MedPAC Report to the Congress: Medicare Payment Policy, March 2018.

<sup>75</sup> MedPAC Report to the Congress: Medicare Payment Policy, March 2019.

<sup>76</sup> MedPAC Report to the Congress: Medicare and the Health Care Delivery System, June 2017.

cannot be considered “unnecessary,” although CMS did not even attempt to analyze their effect.

- Drug Price Inflation. In the CY 2019 OPSS proposed rule there was a table which described the growth in expenditures under OPSS from CY 2010 through 2019. This was used by CMS to justify its proposed policy intended to address “unnecessary” growth in volume in the OPSS. However, a footnote in the table indicated that the growth rates shown included 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% 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.”<sup>77</sup>

In more recent years, per-capita spending on drugs in the United States has grown significantly, with year-over-year growth reaching historically high levels in 2014 (12.4%) and 2015 (8.9%).<sup>78</sup> This growth was driven primarily by changes in drug prices, including both higher launch prices and annual price increases, not utilization.<sup>79</sup> During the past 24 months, growth in spending on prescription drugs has slowed from those historic levels. However, prices have continued to increase for many drugs, while ongoing manufacturing shortages of many prescription drugs have threatened patient access to care.<sup>80</sup>

- Physician Referrals. Some of the increase in outpatient expenditures under the OPSS 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 complete the phase-in of the cut in payment for clinic visits furnished in excepted off-campus PBDs, resulting in payment at the “physician fee schedule (PFS) equivalent” rate of 40% of the OPSS rate. As in 2019, this policy would be implemented in a non-budget

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<sup>77</sup> MedPAC Report to the Congress: Medicare Payment Policy, March 2018.

<sup>78</sup> The National Health Expenditure Accounts

<sup>79</sup> U.S. Department of Labor, U.S. Bureau of Labor Statistics. PPI Detailed Report: December 2017

<sup>80</sup> NORC at the University of Chicago, “Recent Trends in Hospital Drug Spending and Manufacturer Shortages”, Jan. 1, 2019.

neutral manner, which the agency estimates would result in a CY 2020 reduction of \$810 million in hospital payment under the OPSS. **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 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 emergency departments (ED);
- 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, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis; and
- Are 1.1 times more likely to be over 85 years old.<sup>81</sup>

Among Medicare beneficiaries with cancer, the differences in the types of patients seen in HOPDs compared to physician offices is even starker. 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 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, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis.<sup>82</sup>

Hospital representatives have repeatedly warned CMS about the serious implications of its clinic visit policy. At the 2019 Panel meeting,<sup>83</sup> several hospital representatives noted the possible harm that would result if CMS further reduced payments for clinic visits in excepted PBDs. An association representing community cancer centers testified that they “remain deeply concerned about this policy and the harmful effects it could have on access to care if fully implemented. Clinic visits are a central part of care, including

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<sup>81</sup> Source: KNG Health Consulting, LLC analysis of 2010-2016 Medicare Inpatient, Outpatient, and Carrier Standard Analytical Files and Denominator files.

<sup>82</sup> Ibid.

<sup>83</sup> <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

cancer care, and patients rely on hospitals, including off-campus departments, to provide these services, especially in areas with few physician practices. Off-campus departments allow patients to be treated in convenient locations that are integrated with the main hospital. Significantly reducing payment for these services will, without a doubt, hurt hospitals' ability to provide care in these settings." Another hospital representative expressed a concern "about a shift that this may initiate back to the emergency room (ER). We feel like we have been finally able to care for our nonemergency patients away from the ER by going to them out in the community where they are located to provide that care. But we are concerned about the sustainability of those departments as a result of these decreases in reimbursements." Several hospital representatives noted that their hospitals had established off-campus PBDs because they wanted to provide the right care in the right setting and that this often means providing care in the communities in which Medicare beneficiaries live. But the continuation of the payment reduction in off-campus settings would impact their ability to continue to provide this level of care in the community setting, which would reduce beneficiaries' access to these services.

**According to the FY 2017 Medicare cost report data, Medicare margins for outpatient services were negative 14.2% in 2017. Overall, Medicare margins were a record low of negative 9.9% in 2017, with a negative 11.0% projected for 2019.<sup>84</sup> Of note, even "efficient" hospitals had a margin of negative 2% in 2017, according to MedPAC.<sup>85</sup> The site-neutral payment policies implemented by CMS for 2018 and beyond will reduce these margins further.** We are concerned that this, in turn, will threaten beneficiary access to critical hospital-based "safety-net" services and 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.**

This is already occurring, due in no small part to CMS's policies. As spurred by the steady decline in Medicare margins over the past two decades, and as documented by the North Carolina Rural Health Research Program, 113 rural hospitals have closed since 2010, 16 of them in 2019 thus far.<sup>86</sup> 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.**

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<sup>84</sup> MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

<sup>85</sup> Ibid.

<sup>86</sup> <https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures>, accessed Aug 21, 2019.



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

**All of this supports the conclusion that CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted PBDs, repay hospitals for the 2019 payment reduction; and not finalize the proposed 2020 policy.**

## **CONCERN ABOUT INCONSISTENCIES IN CLAIMS DATA BETWEEN 2017 AND 2018**

The AHA also would like to bring an OPSS data-related issue to CMS's attention. We believe that there is a potential issue with the data, and also possibly, with the rate-setting. The issue is that the data appears to be missing a substantial volume of lines with the PN modifier, which indicates a nonexcepted service furnished in an off-campus PBD. That is, in the 2018 proposed rule data, there are approximately 400,000 lines with Healthcare Common Procedure Coding System (HCPCS) codes and the PN modifier. This represents a decline of more than 80% from the 2017 final rule data, which had approximately 2.8 million lines with HCPCS codes and the PN modifier. For benchmarking purposes, we also checked the 2018 100% Outpatient Standard Analytic File (SAF) and found approximately 3.5 million lines with HCPCS codes and the PN modifier. Therefore, the rate-setting data includes substantially less PN modifiers than the SAF data for the same time period. There is not a similar issue with the PO modifier (indicating an excepted service furnished in an off-campus PBD) in the different rate-setting data files.

We realize that the CY 2020 OPSS proposed rule (84 FR 39409) noted that "under the OPSS, CY 2019 was the first year in which claims data containing lines with the modifier 'PN' were available, which indicate nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPSS, in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier 'PN' from the claims data used in ratesetting for the CY 2019 OPSS and subsequent years. For the CY 2020 OPSS, we will continue to remove these claim lines with modifier 'PN' from the ratesetting process." However, despite this logical approach, the 2018 data includes about 400,000 lines with PN, but we identified 2.8 million lines with PN last year.

If the lines with the PN modifier were dropped from the data file and not used in the rate-setting, then the OPSS payment weights would have been calculated correctly. However, we are concerned that if those more than 2 million lines with the PN modifier inadvertently had their modifiers removed and were then used in the rate setting, the OPSS rates would be set improperly. Specifically, if the volume associated with HCPCS code G0463 (included in APC 5012) with the PN modifier dropped by approximately 500,000 cases between 2017 and 2018 but were improperly included in the rate-setting, these erroneous claims would have comprise approximately 1.7% of HCPCS code G0463, and potentially affected APC 5012. And, of course, since all other APC payment weights are set relative to APC 5012, this error would affect the weights of every APC.

**In the interest of ensuring that the weights are set appropriately and consistently each year, we urge the agency to explain in the final rule what occurred in the proposed rule data files and to ensure that the APC payment weights correctly reflect the exclusion of PN modifier claims in the final rule. We also request that CMS clearly documents how it treats lines with the PN modifier and at what stage in the claims accounting released as a part of the rule.**

## **PAYMENTS FOR 340B DRUGS**

HHS has recognized that the United States District Court for the District of Columbia has held that the almost 30% reduction in reimbursement for non-exempt hospitals that participate in the 340B drug savings program was unlawful and inconsistent with the provision of the Medicare Act governing payment for outpatient drugs.<sup>87</sup> Between December 27, 2018, when it issued its decision holding the reduction in payments for 340B drugs unlawful, and July 11, 2019, when it issued its final judgment, the district court had directed the parties to inform the court of the appropriate remedy for HHS's unlawful regulation. In our submission to the court, we explained that any remedy could be based on payments to individual hospitals, and that it was unnecessary to make awards on a claim-by-claim basis. Apparently recognizing the advantages of our approach, HHS has proposed that if the U.S. Court of Appeals for the D.C. Circuit affirms the district court ruling, payments to remedy the unlawful reductions in payments to 340B hospitals could be calculated for each 340B hospital using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 OPSS rules.

**HHS should recalculate the payments due to every 340B-participating hospital that was subject to the reduced OPSS payments for 340B drug claims in 2018 and 2019 to ensure that those hospitals receive the full statutory rate of ASP plus 6% plus interest.** This remedy would not disrupt the Medicare program and is consistent

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<sup>87</sup> 42 U.S.C. § 1395l(t)(14).

with remedies HHS has adopted in past agency violations of law. There is no requirement that an effective remedy be budget neutral.

There Is No Basis for Paying Hospitals Less than the Statutory ASP Plus 6%. Under OPSS statute, HHS must reimburse hospitals for covered outpatient drugs at ASP plus 6%; this was the methodology that HHS used from 2013 to 2017. The statute provides that HHS may “adjust” that statutory rate “as necessary for purposes of [the] paragraph” establishing those rates. HHS has requested comment on adjusting the payment for 2018, 2019 and 2020 from ASP plus 6% to ASP plus 3%, offering as a rationale its desire to impose a payment reduction “at the upper end” of the court imposed “limit [on] the size of the payment reduction the agency can permissibly apply,” “given the substantial discounts that hospitals receive through the 340B program.” [p. 346] While HHS has some authority to deviate from the statutory benchmark of ASP plus 6%, as the district court held, that authority cannot be de-coupled from the provision authorizing HHS to make adjustments, 42 U.S.C. § 1395l(t)(14)(A)(iii)(II).<sup>88</sup> HHS’s description of its rationale demonstrates that it is not an adjustment to more accurately and fairly implement the statutory default rate of ASP plus 6%, as required by section 1395l(t)(14)(A)(iii)(II), but rather one designed to address acquisition cost because HHS has made a policy judgment that the discounts that Congress required in the 340B program are excessive. Because the rationale is inconsistent with the statute, a reduction of the payment from ASP plus 6% to ASP plus 3% would be unlawful.

Calculation of the Amount Due Based on Hospital 340B Claims is a Straightforward and Easily Administered Method of Providing a Remedy to Hospitals. As HHS appears to recognize, there is a straightforward method by which the department can make whole all affected hospitals. The remedy is easy to implement, will not have disruptive consequences for the Medicare program, does not require new rulemaking, and is comparable to actions that other courts and HHS have taken in the past to correct previous unlawful payments to Medicare providers.

As HHS recognizes in its proposed rule, it can recalculate the payments due to 340B hospitals for claims to ensure that those hospitals receive payment based on the statutory rate of ASP plus 6% provided by the 2017 OPSS rule (although as noted above, HHS requested comment on reducing the payments to ASP plus 3%). Hospitals that have already received partial payment should receive a supplemental payment for those claims in an amount that equals the difference between the amount they received and the amount they are entitled to (based on the ASP plus 6% methodology), plus interest. Claims that have not yet been paid should be paid in the full amount (the amount they would have received under the statutory default, ASP plus 6%).

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations can and should be done on a hospital-by-hospital basis rather than on a claim-by-claim basis. Once the

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<sup>88</sup> *AHA v. Azar*, 348 F. Supp. 3d 62, 82 n.16 (D.D.C. 2018).

total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor, which will be uniform across hospitals, to determine how much the hospital should have been paid and thus how much the reimbursement to the hospital was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest.

There is Ample Precedent for Full Retroactive Adjustments that are Not Budget Neutral.

As HHS appears to recognize, if the D.C. Circuit affirms the district court's decision, HHS will be required to reimburse hospitals for underpayments. There is ample authority for HHS to remedy the underpayments caused by its unlawful rule. Indeed, the courts and HHS have provided comparable remedies in equally and more complicated cases. See, e.g., *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid); *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1 (D.D.C. 2018), *appeal dismissed*, 2019 WL 668300 (D.C. Cir. 2019), (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that had started to receive a statutorily mandated adjustment a year later than the statute required); and *Shands Jacksonville Medical Center v. Burwell*, 139 F. Supp. 3d 240 (D.D.C. 2015), (HHS compensated hospitals for three years of across-the-board cuts by adopting a one-time, prospective increase of 0.6%).

As authority for applying budget neutrality to any court required payment to reimburse hospitals for the unlawful reduction in reimbursements for expenditures on 340B drugs, HHS cites subparagraph (H) of paragraph (14) of the OPPI statute.<sup>89</sup> But subparagraph (H), which applies only to "expenditures resulting from this paragraph," namely paragraph (14), has no applicability since the additional expenditure at issue would be required by a judicial decision rather than by paragraph (14)(H) of the statute. In addition, insofar as we are aware, the HHS has never invoked subparagraph (H) to make budget neutrality adjustments further supporting our contention that it has no authority to do so here.

The government underscored the questions about the appropriateness of invoking budget neutrality with respect to payments under paragraph (14) during oral argument in the D.C. Circuit in *AHA v. Azar*, 895 F.3d 822 (2018), when counsel admitted she was "not sure that [the government] would say that all adjustments need to be budget neutral under [the OPPI provision establishing payments for separately payable drugs at issue here]." And, they certainly need not be budget neutral when they fix a prior, unlawful underpayment. In fact, HHS has a policy that allows for retroactive correction of the wage index without any budget neutrality adjustment when the error was due to something HHS did and not something a hospital could have known about and sought to have corrected on its own. Moreover, not all changes in expenditures under the OPPI system must be budget neutral. For example, budget neutrality does not apply to

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<sup>89</sup> 42 U.S.C § 1395l(t).

changes in enrollment or utilization or with respect to drugs when the average sales price increases.

Both case law and agency precedent conclusively demonstrate that HHS is able to make retroactive payments to remedy its illegal behavior and hold others harmless without running afoul of any supposed budget neutrality requirement.

HHS Should Make It Clear that Hospitals Have the Authority to Forego Collecting the Difference Between the Patient Copays Due Under the New Full Reimbursement Rate and the Reimbursement Provided Under the Unlawful Regulation. Under the Medicare Act, HHS reimburses hospitals for 80% of the payment for specified covered outpatient drugs allowable under the statute. The remaining 20% is collected from the patients or their insurance. If HHS reimburses hospitals for the difference between the lawful payment rate and the rate for 2018 and 2019 with a 30% reduction, then in theory hospitals could collect from patients or their insurance companies the difference between 20% of the lawful payment rate and the 20% copay that was actually collected under the 2018 and 2019 OPDS regulations. HHS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

We do not believe that there is any law that would prohibit hospitals from deciding not to collect these payments. The False Claims and anti-kickback statutes would not apply since a retroactive forgiveness in this circumstance would not induce patients to seek services from these providers and thus would not cause an increase in payments for services by the government. Patients who reasonably believe that they have fully paid for hospital care provided months, or in some cases years ago, should not have to make these payments if hospitals are willing to forego them. We urge HHS to state in the final rule that hospitals may forego collecting these payments.

## **PROPOSED PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOPD SERVICES**

Citing its authority under section 1833(t)(2)(F)<sup>90</sup> of the SSA, CMS proposes to implement a prior authorization requirement for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation. The agency claims that these services have had an “unnecessary increase in the volume of services” and that a prior authorization policy would help to ensure these services are billed only when medically necessary.

**The AHA opposes CMS’s proposal to implement a prior authorization requirement for these services and urges the agency to withdraw it. Our concerns are:**

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<sup>90</sup> “(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.”

- **This proposal is contrary to the statute and arbitrary and capricious because the agency must implement any methods developed under paragraph (t)(2)(F) through other provisions of the OPSS statute and the agency has not established that the increase in volume for these services is “unnecessary.”**
- **Even if some of the increase in volume was due to medically unnecessary services, there are several existing processes CMS could use to verify medical necessity instead of imposing a new and costly prior authorization process that runs completely contrary to the agency’s goal of reducing regulatory burden.**
- **It is unclear why CMS proposes to impose a prior authorization process only on hospitals, when it is physicians who order and furnish the services that the agency claims have experienced an “unnecessary” increase in volume.**

Section 1833(t)(2)(F) does not provide CMS authority to impose prior authorization on select services. As noted, CMS rests its authority to require prior authorization for five categories of services on section 1833(t)(2)(F) of the OPSS statute, which requires CMS to develop a method under OPSS for controlling unnecessary increases in the volume of covered HOPD services. But that provision does not confer on CMS any authority to adopt prior authorization. Indeed, section 1833(t)(2)(F) does not confer independent authority whatsoever. As the federal district court for the District of Columbia recently explained when addressing CMS’s clinic visit policy, “Congress did not intend CMS to use an untethered ‘method’ to directly alter expenditures independent of other processes. To the contrary, Congress directed that any ‘methods’ developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.”<sup>91</sup> Here, CMS can point to no other provision of the OPSS statute that would authorize a prior authorization requirement. As a result, the proposal is contrary to law and CMS has exceeded its authority.

In addition, the proposal is arbitrary and capricious because CMS has not met the statutory requirement that it establish that the increases in volumes for these HOPD services are “unnecessary.” In the proposed rule, CMS describes claims data for an 11-year period from 2007 through 2017 showing increases in the volume of service utilization for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation. CMS asserts that the increases in volume for these services are unnecessary because: (1) the data show that the volume of utilization of these services exceeds what would be expected in light of the average rate of increase in the number of Medicare beneficiaries; (2) these procedures are often considered cosmetic and, in those instances, would not be covered by Medicare; and (3) the agency is unaware of other factors that might contribute to clinically valid

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<sup>91</sup> *AHA et al. v. Azar*, No. 18-CV-2841, at \*25 (D.D.C. Sept. 17, 2019).

increases in volume, such as “clinical advancements or expanded coverage criteria that would have led to the increases.”

**While CMS presents data on increases in the volume of these services, the agency has not demonstrated that these volume increases are “unnecessary.” Further, CMS fails to meaningfully seek out or analyze any alternative explanation for the increase in volumes it reports, instead it merely notes that it is “unaware of other factors” that could explain it. These failings make the proposed prior authorization requirement arbitrary and capricious.**

It is “well established” that an agency has a duty to consider reasonable alternatives to its chosen conclusions and courses of action.<sup>92</sup> An agency may not adopt an “ostrich-like approach” to decision-making,<sup>93</sup> where “[n]ot having discussed the [alternative] possibilit[ies], the agency submit[s] no reasons at all” for why it adopts its explanation over other reasonable alternatives.<sup>94</sup>

In this case, the universe of reasonable alternative explanations includes, among other things, the possibility that volume is increasing because clinically appropriate and medically necessary demand is increasing.

As discussed below, there are medically necessary indications for each of the procedures that would be subject to prior authorization and, in fact, there have been well-publicized clinical improvements and expanded approved uses for some of these procedures that could help explain the increases in volume. For example:

- *Blepharoplasty* is the plastic surgery operation for correcting defects, deformities, and disfigurements of the eyelids. As some people age, the eyelid droops so much it covers part of the eye so the patient has a partially obscured visual field. This can make activities of daily living, like driving and reading, difficult and cause vision difficulties that increase the risk for falls. Among the conditions for which blepharoplasty would be medically necessary are ptosis, pseudoptosis, blepharochalasis, dermatochalasis, periorbital sequelae of thyroid disease, anophthalmic socket, blepharoptosis, brow ptosis, and horizontal eyelid laxity. Further, while the agency claims that there has been an unexpected increase in the volume of blepharoplasty procedures over an 11-year period, it does not set forth any actual data analyses or number in the rule. However, an analysis by the AHA using the average number of units for each of the procedures within the blepharoplasty group per beneficiary showed virtually no increase in volume over this time period. See Table 1 below. This finding calls into question the basis for CMS’s claim of increasing volume and costs and casts doubt on the prior authorization proposal.

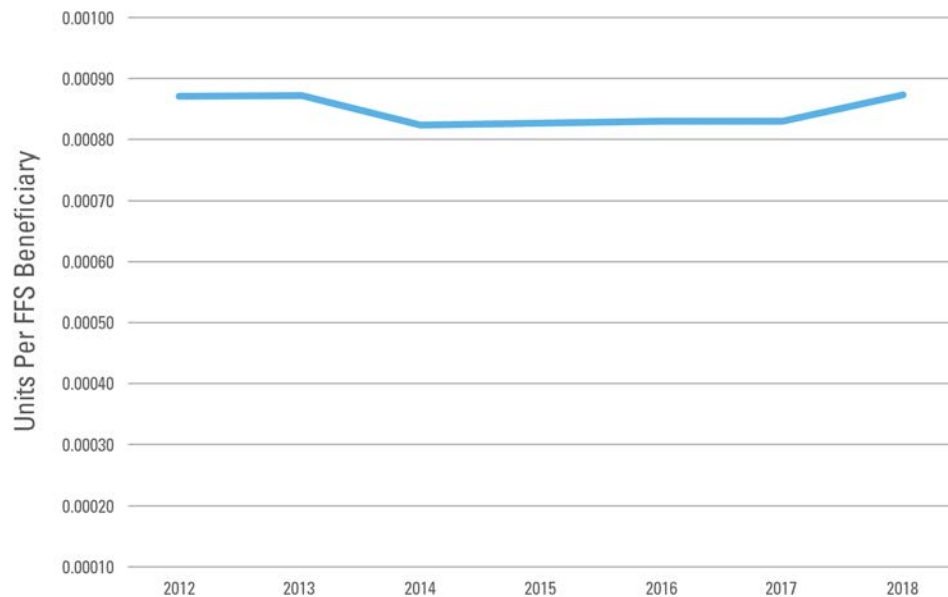
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<sup>92</sup> *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1511 (D.C. Cir. 1984)

<sup>93</sup> *Portland Cement Ass’n v. EPA*, 665 F.3d 177, 185 (D.C. Cir. 2011)

<sup>94</sup> *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983)

**Table 1: Blepharoplasty**



- *Botulinum toxin injections* were approved by the Food and Drug Administration (FDA) in 2010 for the treatment of chronic migraines and for the treatment of upper limb spasticity adults, but the use of this product for these indications likely took a number of years to be widely accepted, with the volume gradually growing as physicians and patients understood it to be an option. Since then, FDA approved other uses for botulinum toxin injections, including for the treatment of a specific form of urinary incontinence (in 2011), to treat overactive bladder (in 2013), for the treatment of lower limb spasticity (in 2016). It also is used to treat eye muscle problems (strabismus) and uncontrolled eyelid twitching (blepharospasm). These clinical advances in the use of botulinum toxin could explain the increase in the volume of utilization for these procedures over time.
- *Panniculectomy* is a surgical procedure to remove the excess skin and tissue from the lower abdomen. This procedure is medically necessary for the treatment of chronic and persistent skin conditions, such as intertriginous dermatitis, panniculitis, cellulitis, or skin ulcerations. In addition, morbid obesity, often a precursor to the need for panniculectomy, is increasing in prevalence, creating a problematic public health concern. Given that at least one third of U.S. adults, including older adults aged 65 and over, have a Body Mass Index greater than 30, and the prevalence of obesity is increasing<sup>95</sup>, referrals to surgeons for obesity-associated conditions will continue to rise. One of these is for panniculus morbidus, a condition characterized by a massive abdominal apron of skin and soft tissue that is commonly found in morbidly obese and bariatric patients after massive weight loss, which makes them prone to chronic infection at the skin

<sup>95</sup> <https://www.ncbi.nlm.nih.gov/books/NBK532533/>.



folds, dermatitis, ulceration, sinus tract formation and lymphedema, among other conditions. The treatment for panniculus morbidus remains surgical, often involving panniculectomy. Clinical improvements in panniculectomy have occurred in recent years, especially new techniques to assist the surgeon in obtaining adequate exposure to increase efficiency during dissection, prevent inadvertent vessel injury and identify if hernias are present.<sup>96</sup> The combination of the increasing prevalence of morbid obesity, along with its sequelae, and the clinical improvements in panniculectomy may explain the increase in the utilization volume of this procedure.

- *Rhinoplasty* is a plastic surgery procedure for correcting and reconstructing the form and functions of the nose. The procedure is often medically necessary when its intent is to enhance function by improving nasal respiration and relieve an obstruction that is congenital or acquired. It would be medically necessary for a variety of conditions such as a deviated nasal septum, chronic sinusitis, traumatic injury of the nose, nasal obstruction, and to correct a nasal deformity secondary to congenital cleft lip or cleft palate. A growing body of evidence supports methods to optimize care in the perioperative period regardless of the specific anatomy corrected or technique used.<sup>97</sup> For example, studies<sup>98,99</sup> assessing advances in the procedure, including pre- and intraoperative administration of analgesics, resulted in lower postoperative pain scores and less postoperative pain medication consumption. Such recent clinical advances in reducing postoperative pain from rhinoplasty may explain utilization volume increases among Medicare beneficiaries.
- *Vein ablations* are procedures used to close the abnormal veins that lead to varicose veins. Among the medically necessary reasons for this procedure are venous stasis ulcer, pain and edema associated with saphenous reflux, bleeding associated with ruptured superficial varicosity, recurrent episodes of superficial phlebitis, stasis dermatitis, refractory dependent edema, saphenous vein reflux, venous incompetence and venous reflux/venous insufficiency. Furthermore, during the last several years, clinical advances such as new forms of compression, advanced wound dressings, and minimally invasive techniques with lower morbidity have been developed and may be a factor in increased utilization volume for vein ablation procedures. A publication, “Latest Innovations

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<sup>96</sup> Abdominal suspension during massive panniculectomy: A novel technique and review of the literature; A. Graf, K Yang, K. Klement, N. Kim, H. Matloub; JPRAS Open, Vol. 8, P. 23–28, June 2016.

<sup>97</sup> Clinical Practice Guideline: Improving Nasal Form and Function after Rhinoplasty, Lisa E. Ishii, MD, MHS, Travis T. Tollefson, MD, MPH, Gregory J. Basura, MD, PhD; Otolaryngology–Head and Neck Surgery; Volume: 156 issue: 2\_suppl, page(s): S1-S30; February 1, 2017.

<sup>98</sup> Demirhan, A, Tekelioglu, UY, Akkaya, A. Effect of pregabalin and dexamethasone addition to multimodal analgesia on postoperative analgesia following rhinoplasty surgery. *Aesthetic Plast Surg.* 2013;37(6):1100-1106.

<sup>99</sup> Ozer, AB, Erhan, OL, Keles, E. Comparison of the effects of preoperative and intraoperative intravenous application of dexketoprofen on postoperative analgesia in septorhinoplasty patients: randomized double blind clinical trial. *Eur Rev Med Pharmacol Sci.* 2012;16(13):1828-1833.

in the Treatment of Venous Disease”<sup>100</sup> describes clinical improvements that may be useful to CMS in understanding the increased medically necessary utilization of vein ablation procedures.

Given the increased burden associated with prior authorization, CMS should consider other existing processes to verify medical necessity. Imposing a new, onerous and costly prior authorization process in the OPPS would be premature and unnecessary. CMS should not be using limited government resources to build bureaucratic infrastructure that runs completely counter to its stated goal of reducing regulatory burden. It would be especially inappropriate to implement a nationwide prior authorization program when similar prior authorization programs have not been proven to substantially decrease medically unnecessary services. As we have seen with Medicare Advantage and Medicaid, poorly structured or implemented prior authorization programs create unnecessary and excessive burdens on providers and, worse, delays in patient care that can negatively impact patients. For example, hospitals spend a considerable amount of resources appealing inappropriate claims denials by Medicare Advantage plans and when beneficiaries or providers appealed, plans overturned 75% of their own rulings at the first stage of appeal, suggesting that many of these denials were inappropriate in the first place.

Instead, there are several existing processes Medicare could use to help ensure that only medically necessary services are paid under Medicare. These processes should be used first to reduce the need for prior authorization. Among these are:

- *Local or National Coverage Determinations.* Many of these services already are subject to a local coverage determination (LCD). In order to better ensure that the rules for coverage of medically necessary procedures are clear up front, CMS could develop national coverage determinations (NCDs) or encourage its Medicare Administrative Contractors (MACs) to develop additional LCDs for those procedures without one already.
- *Target, Probe, Educate (TPE) Program.* CMS could instruct MACs to conduct TPE reviews for procedures the agency is concerned about. The TPE program is designed to help physicians and providers reduce claim denials and appeals through one-on-one help where MAC’s review claims and if they find an issue, they provide education with the provider or supplier, giving them a chance to improve.

CMS has not adequately thought through this proposal. CMS proposes to create a prior authorization process only for hospitals under the OPPS. However, hospitals don’t order these procedures that the agency claims have experienced an “unnecessary” increase

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<sup>100</sup> Latest Innovations in the Treatment of Venous Disease; Robert R. Attaran; J Clin Med. 2018 Apr; 7(4): 77; published online April 11, 2018.

in volume. CMS should be aware that often it is the failure of the ordering physician to provide sufficient documentation to support medical necessity that results in subsequent claims review, denial or payment recovery from the provider. For example, in a report<sup>101</sup> about a Comprehensive Error Rate Testing (CERT) program special study of claims for blepharoplasty, conducted from January through March 2015, every example of improper payment identified in the report was due to either the physician (ophthalmologist) or ASC failing to submit adequate documentation that the service was reasonable and necessary.

Although justifying that a service is reasonable and necessary will depend on documentation that only the ordering physician can provide, there is nothing in the PFS rule that applies the proposed prior authorization process to the ordering physician or otherwise imposes any obligation on the physician to provide such documentation. Under CMS's proposed prior authorization process, if the ordering physician does not follow the process to provide adequate documentation confirming medical necessity, it is the hospital that is at financial risk. It is not even clear if the physician's claim for the service would be denied in these circumstances. The proposed rule also would not apply a prior authorization process to ASCs.

## **PROPOSED CHANGES IN THE LEVEL OF SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS (CAHs)**

CMS proposes to change the minimum required level of supervision from direct supervision to general supervision for hospital outpatient therapeutic services provided by all hospitals and CAHs. This proposal would ensure a standard minimum level of supervision for each hospital and CAH outpatient service furnished incident to a physician's service. **The AHA strongly supports this proposal, as we have repeatedly urged CMS for such a solution to this critical issue for rural hospitals.**

We agree with CMS's reasoning in proposing this policy, including that:

- there has been no data or information from CAHs and small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by the nonenforcement instruction that the agency has had in place since 2009, which resulted in general supervision being the default level of supervision during these years;
- a minimum requirement for general supervision does not preclude hospitals from providing direct supervision for specific outpatient therapeutic services when the

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<sup>101</sup> <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedQtrlyComp-Newsletter-ICN909346.pdf>

physicians ordering or administering the medical procedure decides that it is appropriate to do so;

- there are other requirements that apply to hospitals and physicians which complement the general supervision requirements and help ensure that the medical services Medicare patients receive are properly supervised, such as the hospital and CAH conditions of participation (CoPs) and state scope of practice laws; and
- the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers, particularly CAHs and small rural hospitals, which reduces their flexibility to provide medical care in a manner best suited to the needs of their patients.

The AHA also supports CMS's intent to have the HOP Panel continue to review and provide recommendations to CMS on the appropriate supervision levels for individual hospital outpatient therapeutic services and for the agency to retain its authority to make changes to the level of supervision required for individual outpatient therapeutic services through notice-and-comment rulemaking.

## **AREA WAGE INDEX**

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. As it has done in previous years, CMS proposes to adopt the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for the OPSS. Among the finalized policies in the inpatient rule is an increase in the wage index for hospitals with a wage index value below the 25th percentile.

Specifically, CMS increases the wage index values for these hospitals by half the difference between the otherwise applicable wage index value for the hospital and the 25th percentile wage index value for all hospitals. CMS adjusts the standardized amount in order to make this policy budget neutral. As applied to the OPSS, CMS would make this policy budget neutral by adjusting the conversion factor.

**As outlined in AHA's previous [comments](#), we appreciate CMS's recognition of the wage index's shortcomings and support improving the wage index values for low-wage hospitals. However, this should not be accomplished by further reducing Medicare payments, especially in light of the fact that Medicare currently reimburses all PPS-participating hospitals below the cost of care. As such, we support increasing the wage index values of low-wage hospitals, but continue to urge the agency to use its existing authority to do so in a non-budget neutral manner.**

## PROPOSED CHANGES TO THE INPATIENT-ONLY LIST

For CY 2020, CMS proposes to remove CPT code 27130 (Total Hip Arthroplasty (THA)) from the inpatient-only list. **The AHA opposes the removal of THA from the inpatient-only list. We do not believe it would be clinically appropriate to do so and are concerned that it could put the success of the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payments for Care Improvement (BPCI) programs at risk.**

We are concerned that removing THA from the inpatient only list would pose serious risks and would have negative quality of care implications for vulnerable Medicare patients. THA is a complicated, invasive surgical procedure, with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period. While these procedures may be successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated.

Further, patients who undergo THA experience significant post-operative pain, which AHA believes is best managed in inpatient settings. Managing post-operative pain for THAs performed in outpatient settings affects the ability to get appropriate and timely ancillary support, which is exacerbated by socioeconomic barriers that can often result in delays in care. We believe that there likely would be few, if any, Medicare beneficiaries who could safely be discharged home the same day after undergoing a THA, as would occur if this procedure were furnished in a hospital outpatient setting. Providing this surgery in an outpatient setting will not afford patients enough time to recover properly or allow providers to address all post-surgical concerns — including any problems that arise with comorbidities. There is significant concern with ensuring that Medicare patients would be able to be discharged into a safe home environment, creating potential issues with patient safety and an increase in hospital admissions.

With regard to CJR and BPCI, hospitals share CMS's goal of achieving success under these programs, not only for themselves, but also for Medicare and its beneficiaries. **As such, we are concerned that the agency did not present any proposals to modify the CJR and BPCI initiatives if the THA procedure were moved off the inpatient-only list, especially since the agency itself has noted in the past the problems that could arise if this were not addressed properly.** Specifically, shifting the less medically complex Medicare THA population to the outpatient setting would increase the risk profile of the inpatient Medicare THA population. This would, in turn, create an apples-to-oranges comparison within bundling programs when evaluating hospitals' actual expenditures versus their historical target prices. Performance under the programs would be inappropriately negatively impacted, potentially to a large degree. Indeed, we raised similar concerns when the agency removed total knee arthroplasty (TKA) from the inpatient only list — concerns which we have seen borne out. For

example, one major health system saw a 30% reduction in its CJR volume when TKA was removed from the inpatient only list. They are concerned that this low volume and the fact that their remaining patients are more severely ill is putting their success in the program in jeopardy.

**Notwithstanding our clinical concerns, we strongly urge the agency to modify the CJR and BPCI programs to account for the removal of THA from the inpatient-only list if it were to finalize such a policy.** As we have previously [suggested](#), the agency could do so either by incorporating a comprehensive risk-adjustment methodology, and/or by evaluating whether to include *outpatient* THA in the programs.

### **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, and using more current data to again evaluate whether there are payment incentives for using opioids instead of non-opioid alternatives, CMS proposes to continue its policy 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 continuing this policy 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 HOPDs.

The AHA appreciates that CMS is engaging stakeholders to investigate novel strategies to address the opioid crisis. We continue to 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.

**However, the current packaged payment for such non-opioid alternatives in HOPDs continues to present a barrier to access to care and therefore warrants separate payment under OPPIs as well. Therefore, we continue to support the ASC 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 continues to support 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 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 CALCULATION AND USE OF COST-TO-CHARGE RATIOS**

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 and 2019.

In the CY 2020 proposed rule, the agency says that it believes that it has provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if it intended to do so. **Therefore, CMS proposes that for CY 2020 it will use all claims with valid CT and MRI cost center CCRs, including those that use a “square feet” cost allocation method, to estimate costs for the APCs for CT and MRI procedures.**

CMS presents data showing that if the agency ends the transition and uses 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. In addition, the agency states that there is a potential impact that the CT and MRI CCRs may have on other payment systems. That is, payment reductions for imaging services under the OPSS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPSS payment amount. The agency notes it will continue to monitor OPSS imaging payments in the

future and consider the potential impacts of payment changes on the PFS and the ASC payment system.

**The AHA urges CMS to extend its transitional policy of excluding providers that use the square foot cost allocation methodology in calculating the OPPS relative weights for at least one additional year and encourages the agency to continue to educate providers about the benefits of switching to a more accurate cost allocation method. If CMS is not willing to do so then we recommend that the agency phase-in the resulting payment reductions over a two or more year period.** We are concerned about the possible implications that a sudden and significant drop in reimbursement — in fact an inappropriate underpayment for these services — would have for access to CT and MRIs not only in HOPDs paid under the OPPS but also in independent diagnostic testing facilities and ASCs that would also be impacted. Imaging services such as these are critical tools needed to properly diagnose and develop plans of care for Medicare beneficiaries. For instance, we encourage CMS to engage stakeholders, including hospital associations, the Healthcare Financial Management Association, the American College of Radiology, and other groups, to develop materials and tools that can be used to raise awareness about this issue and to offer solutions. The AHA would be pleased to be a partner in such an effort.

## **POTENTIAL REVISIONS TO THE OPPS PAYMENT POLICY FOR SKIN SUBSTITUTES: COMMENT SOLICITATION FOR CY 2020**

Since CY 2016, CMS has used the high-cost/low-cost status for each skin substitute product, based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) exceeding the PDC threshold. For CY 2020, CMS proposes to continue to assign skin substitutes to the high cost/low cost categories and retain a high cost product in the high cost category for at least two years even if the cost data shows that the product should be reassigned to the low cost category.

However, CMS again requests public comments on two alternative methodologies intended to improve pricing stability for skin substitutes that it will consider for future OPPS rulemaking. These include establishing an "episode-based" payment for a wound care episode and eliminating the high-cost/low-cost categories and replacing them with only one payment category and set of procedure codes for the application of all graft skin substitute products.

The AHA does not recommend that CMS pursue either the episode-based payment or the establishment of a single payment category. In particular, we do not believe that CMS has sufficient experience with episode payment and should not pursue this until much more data related to packaged payment and analysis of packaging policies is performed. Further, we are concerned that a single payment category would not provide



the right financial incentives to promote the use of the wide variety of skin substitute products in the most clinically appropriate manner.

**Instead, the AHA recommends that CMS consider adding new C-APCs for skin substitute procedures.** We note that this is consistent with a recommendation made by the HOP Panel at its August meeting that “that CMS consider creating a comprehensive APC for skin substitute products.” We recommend that the C-APCs be paid on a per-encounter basis and not on a per-episode basis. Many of the wound care (debridement) procedures are already in a C-APC. CMS could evaluate the different skin substitute product codes with the procedures as well as the add-on procedure codes for complexity adjustments. In this way, CMS would have more wound care claims and total claim cost data to use in the development of the C-APC payment rates. The AHA believe this would result in more accurate payment while also incentivizing providers to use the most cost-effective product for the clinical indication.

## **HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM**

CMS proposes to remove one measure from the OQR program beginning CY 2022, and also requests feedback on potentially adopting four patient safety measures currently adopted in the ASC Quality Reporting Program (ASCQR).

Removal of OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases. **The AHA supports CMS’s proposal to remove this measure. 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 with all of the concerns regarding this measure listed by CMS in the proposed rule, primarily that the measure’s exclusions are overly complex and the manual patient record reviews necessary to calculate measure performance are administratively burdensome. Further, as the measure steward is no longer maintaining the measure, we agree with the agency that the measure may no longer be aligned with clinical guidelines and standards. **We urge CMS to remove this measure beginning Jan. 1, 2020 rather than beginning with October 2020 encounters for the CY 2022 payment determination; this payment determination is based on reporting for CY 2020 data, so if the data will not inform payments in 2022, there is no reason for HOPDs to collect if for January through September 2020.**

We are pleased that CMS has significantly streamlined the measures in the OQR; in the CY 2019 final rule, the agency finalized the removal of eight measures from the program. However, CMS could do even more to update the OQR and focus only on measures that encourage improvements in hospital quality. For example, CMS could prioritize removal of measures that have either lost endorsement by the National Quality Forum (NQF) or never received endorsement in the first place. 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 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 unreasonably difficult to collect should not be included in Medicare quality reporting programs. **Thus, the AHA again urges CMS to consider including the lack of NQF endorsement as a ninth measure removal factor for the OQR and other measurement programs.** 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 Nov. 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)

We understand that due to CMS's efforts to focus only on Meaningful Measures, the CY 2022 OQR has very few measures remaining. The removal of outmoded measures is an essential part of getting to the "measures that matter" the most to improving care. At the same time, it also is important for CMS to address high-priority gap areas, and we appreciate that the agency is working with several stakeholders to develop new measures for the outpatient setting. **With this in mind, we recommend 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 and behavioral 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.

We gladly offer our assistance in these efforts and hope to continue collaborating with CMS to improve the OQR.

Potential Future Adoption of ASC Patient Safety Measures. CMS seeks feedback on potentially adopting four patient safety measures for the OQR that were previously

adopted — but whose reporting is currently suspended — in the ASCQR. These measures include ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC-4: All-cause Hospital Transfer/Readmission. We appreciate CMS's interest in measures related to patient safety, and believe the issues reflected in the measures merit ongoing surveillance. **However, the AHA does not believe that adding these measures to the OQR would achieve CMS's goal of Meaningful Measurement.**

For measures to be suitable for a national reporting program, they should focus on quality or safety issues that apply to a wide range of facilities, occur frequently and have substantial performance variation across the field. Yet, for the most part, the events captured in ASC 1-4 are described by CMS and others in the quality field as “never events”: serious and usually preventable events in the provision of health care services that should never occur. Because these are preventable and serious, their incidence is rare, especially in the HOPD setting. Furthermore, hospitals already are held to a variety of requirements — including those from Medicare's CoPs and accrediting organizations — to implement policies and processes to mitigate the risks of these events. In addition, more than 25 states and the District of Columbia have mandatory reporting of never events, and the majority require facilities to conduct root cause analyses and implement corrective action plans. Hospitals have their own extensive internal surveillance systems to identify serious safety events and analyze them for opportunities for system change. Lastly, it is important to note that reporting of the measures was suspended in the ASCQR because they did not produce accurate data. Adding four measures that report on rare events inaccurately seems incongruous with CMS's stated desire to move toward meaningful measurement.

We also note that NQF endorsement for all four measures has been removed. While CMS notes that endorsement “was allowed to lapse by the measure steward, not because they failed the endorsement maintenance process,” we think this is a distinction without a difference: the four measures are not endorsed by the NQF and have not undergone recent updating to ensure that their specifications are reliable, valid, and in line with clinical standards, and thus should not be adopted in a CMS program until and unless they are.

In addition to questioning the usefulness of these measures in the OQR, we have concerns regarding the logistics of using ASC-specified measures in the OQR. According to its proposal, CMS suggests that if it were to adopt these measures in the OQR, the measure would be reported through a CMS online data submission tool, like the QualityNet site that is currently used to report other quality data. We understand CMS's rationale behind this proposal, as the current method that ASCs use to report this data — submission of certain quality data codes (QDCs) on claims with a low threshold for satisfactory reporting — negatively impacted the completeness and accuracy of the data. However, we question whether QualityNet (or a similar online submission tool) would be able to handle the high volume of data submitted for four measures by HOPDs in addition to ASCs if these measures were adopted and

reinstated in the ASCQR, especially if HOPDs had to report patient-level rather than aggregate data. Every year, our members report significant issues with upload times, error messages, and dropped connections with QualityNet, and we imagine these problems would be exacerbated under this proposal.

CMS also notes in its proposal that, while the measures are currently specified for the ASC setting, the agency is “considering having them specified for the hospital outpatient setting.” If CMS were to move forward with this proposal, it would have to do more than “consider” using appropriate specifications. ASCs and HOPDs are not directly comparable; HOPDs treat sicker and more vulnerable patients, and are hospital facilities with different staffing, processes and procedures, and resources. In light of these issues, we are skeptical that ASC measures that have not been specified or tested in HOPDs would produce reliable data because HOPDs collect and report data differently than ASCs.

All that said, we appreciate CMS’s focus on patient safety, and would be glad to work with the agency to try to identify measures that reflect more pressing and prevalent issues in the HOPD setting. As always, the AHA stands ready to work with the agency to advance a range of programs and policies — including those outside of its measurement programs — to make care safer.

## **PROPOSED ADDITIONS TO THE LIST OF ASC-COVERED SURGICAL PROCEDURES**

CMS proposes to add eight procedures to the ASC list of covered surgical procedures, including a TKA procedure and a mosaicplasty procedure, as well as three coronary intervention procedures and three related add-on procedures. CMS also seeks comments on whether 14 other coronary intervention procedures should be added to the ASC list of covered surgical procedures.

**The AHA urges CMS not to finalize its proposal to add any of these procedures to the list of ASC-covered procedures because they may impose a significant safety risk to Medicare beneficiaries when performed in an ASC.** Our specific concerns are discussed further below.

TKA Procedure Proposed for Addition to the List of Covered ASC Procedures for CY 2020. CMS indicates that in light of the information it received from commenters in support of adding TKA in the CY 2018 OP/ASC proposed rule, it believes TKA would meet Medicare regulatory requirements for covered surgical procedures in the ASC setting. Therefore, CMS proposes to add two knee arthroplasty services to the list of ASC covered procedures for CY 2020, including TKA and mosaicplasty procedures.

**The AHA opposes adding TKA to the ASC list. We believe it is neither safe nor clinically appropriate for Medicare beneficiaries to receive such major surgical procedures in ASCs.** TKA is a complex surgical procedure which, while it may be

successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population. As noted above, nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living (ADL) that limit their ability to function independently. These co-morbid conditions and ADL limitations make even simple procedures more complicated. In addition, spinal anesthesia often is used for TKAs and waiting for full sensation to return can take hours. Finally, pain management, particularly in the immediate postoperative period, remains a challenge. Management of postoperative pain is controlled best in the acute care hospital setting.

Further, CMS acknowledges in the proposed rule that TKA procedures were still predominantly performed (82% of the time) in the inpatient hospital setting in CY 2018 and that the majority of beneficiaries may not be suitable candidates to receive TKA in an ASC setting. We wholeheartedly agree and believe that this statistic should give CMS enough pause to act on the side of caution as it would be a patient safety risk for vulnerable Medicare beneficiaries to have these surgical procedures in ASCs.

While complications related to TKA are uncommon, they include certain devastating, life-threatening events. Among other possible complications, patients undergoing TKA are at increased risk of myocardial infarction<sup>102</sup> (patients are 80 years or older are at highest risk<sup>103</sup>) and at risk for the development of deep vein thrombosis with the potential to propagate a potentially lethal pulmonary embolus.<sup>104</sup> There also are complications associated with any major surgery, such as anesthesia-related risks, allergic and other medication reactions, and those related to comorbid medical conditions.<sup>105</sup> ASCs are simply not equipped to handle such life-threatening events and we anticipate that if CMS finalizes its proposal, many more patients would be sent emergently from ASCs to the nearby hospital ED when such complications arise.

We also note that CMS has proposed to weaken the current ASC Conditions for Coverage (CfCs) requirements that mandate that there is a plan in place in the event such emergencies arise. That is, in the Sept. 20, 2018 Medicare burden reduction proposed rule, CMS proposed to eliminate the requirement that ASCs have a written transfer agreement with a nearby hospital or ensure that its physician have admitting privileges at a hospital. Taking away these reasonable safeguards would put beneficiaries at even further risk. Adding such complex, invasive surgical procedures to

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<sup>102</sup> Lu N, Misra D, Neogi T, et al. Total joint arthroplasty and the risk of myocardial infarction: a general population, propensity score-matched cohort study. *Arthritis Rheumatol* 2015;67:2771.

<sup>103</sup> Belmont, PJ Jr, Goodman GP, Kusnezov NA, et al. Postoperative myocardial infarction and cardiac arrest following primary total knee and hip arthroplasty; rates, risk factors and time of occurrence. *J Bone Joint Surg Am* 2014; 96:2025.

<sup>104</sup> Kim YH, Kim JS. Incidence and natural history of deep-vein thrombosis after total knee arthroplasty. A prospective, randomized study. *J Bone Joint Surg Br* 2002; 84:566.

<sup>105</sup> Martin GM, Roe J, et al. Complications of total knee arthroplasty. *Wolters Kluwer UpToDate* 2019.

the list of covered surgical procedures while simultaneously proposing to weaken protections is not advisable.

Furthermore, we do not believe that the safeguards that CMS suggests would be workable or adequate to ensure that beneficiaries selected to receive TKA in an ASC are clinically appropriate for this setting and that their care is safely provided. First, CMS suggests that it could require that a modifier be included on ASC claims which indicates that the physician believes that the beneficiary would not be expected to require active medical monitoring and care at midnight following a particular procedure furnished in an ASC. We question how a physician could confidently make this determination. Further, merely applying a modifier would not in any way assure the patient's safety. In addition to the inherent risks associated with TKA for older patients, part of our concern is that ASCs are often physician-owned and not subject to the Stark self-referral regulations. Therefore, there may be other incentives in place for physicians in making such a determination.

Second, another potential safeguard that CMS discusses is requiring that an ASC has a defined plan of post-operative care for each beneficiary following a surgical procedure. While attentive postoperative management is critical for success in any complex major surgery, we believe that ASCs, unlike hospitals, generally do not have the case management infrastructure in place to ensure that such plans are carried out. We note that the ASC CfC at §416.52(c)(2) already require written discharge orders<sup>106</sup> but these are designed for the less risky surgical services that are ASCs' bread and butter. It is not clear how ASCs, with regular business-day hours of operation, can ensure that such a plan would adequately safeguard vulnerable Medicare beneficiaries discharged less than 24-hours after such a major surgery, and who are likely in significant pain, unable to walk and potentially facing serious complications. Most likely, hospitals will have to come to the rescue of beneficiaries whose conditions deteriorate after they are sent home from the ASC. However, although not advisable, if CMS were to finalize its proposal to add TKA to the list of covered ASC procedures, we would urge CMS to require that ASCs develop a patient-specific plan of post-operative care for each beneficiary, including a certification that the patient has support at home or elsewhere for post-surgical recovery and possible complications and provides each patient with information about after-hours access to staff at the ASC for question and assistance.

Third, CMS suggests as a potential safeguard establishing certain requirements for ASCs that choose to perform TKAs on Medicare patients, such as requiring an ASC to have a certain amount of experience in performing these procedures before being eligible for payment for performing the procedure under Medicare. While it is widely known that the incidence of some surgical complications may be reduced if the

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<sup>106</sup> [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_1\\_ambulatory.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf)

procedure is performed by a higher-volume physician and hospital, we are unsure how CMS could operationalize such a requirement in ASCs. It may be too burdensome for ASCs, which are not even able to collect and report their costs to the Medicare program. However, although not advisable, if CMS were to finalize its proposal to add TKA to the list of covered ASC procedures, we would urge CMS to institute such minimum experience requirements for ASCs, including minimum annual procedure performance standards for its physicians.

Finally, the AHA notes that CMS presumes that shifting services to “lower-cost” settings, like ASCs, would reduce beneficiary out-of-pocket costs. However, the opposite appears to be true for TKA; beneficiaries will most likely face higher copayments in ASCs than in HOPDs. This is because, unlike in the ASC setting, in the HOPD, the beneficiary copayment amount is capped at the inpatient deductible amount, which is \$1,364 in 2019<sup>107</sup>. In the OPPI, CPT 27447 (TKA) and CPT 29867 (Allograft implant knee with scope) are part of C-APC 5115, Level 5 Musculoskeletal Procedures, proposed to be paid at \$11,960 in CY 2020. Therefore, the 20% copayment for C-APC 5115 (\$2,392) would exceed the Medicare Part A inpatient deductible and would be capped at that amount. By contrast, in the ASC setting, there are no C-APCs or caps on the patient copayment amounts. Every separately payable ancillary service that is furnished in an ASC alongside TKA would be subject to an additional 20% copayment. For CY 2020, CMS proposes a payment rate for CPT 27447 (TKA) of \$8,640, which would result in a copayment of \$1,728. This is already \$364 more than the beneficiary copayment in the HOPD and does not even include all the other separately payable services likely furnished along with a TKA in the ASC setting. Therefore, the out-of-pocket costs for Medicare beneficiaries could be significantly higher in an ASC than in an HOPD.

Coronary Intervention Procedures Proposed for Addition to the List of ASC Covered Services in CY 2020. CMS proposes to add two percutaneous transluminal coronary angioplasty (PTCA) procedures and four percutaneous transcatheter placement of intracoronary stents and drug eluting intracoronary stent procedures to the list of ASC-covered services for CY 2020. The agency believes that, despite the fact that these procedures may involve major blood vessels, they would be safe to perform in an ASC setting. CMS claims that this determination was based on a review of the clinical characteristics of these procedures and their similarity to other procedures that are currently included on the ASC covered procedure list.

**The AHA opposes adding these coronary intervention procedures to the ASC list. Doing so would be unsafe for Medicare beneficiaries and not clinically appropriate in an ASC setting.** We are concerned that these procedures, which involve major blood vessels, could lead to serious complications in ASCs. This would result in more beneficiaries being sent emergently to hospital EDs, putting their lives at risk.

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<sup>107</sup> The 2020 inpatient deductible amount has not yet been announced but will likely increase in 2020.

There are many serious possible complications described in medical literature for PTCA and stenting procedures. Among these are in-facility death, damage to or perforations of coronary arteries, intramural hematoma, distal embolization, stent thrombosis and myocardial ischemia. Further, the risks for complications for percutaneous coronary intervention procedures, including stenting, have been shown to be associated with age and various co-morbidities. By definition, Medicare beneficiaries would be at higher risk, as they are all either over 65 or under 65 and disabled, and nearly half live with four or more chronic conditions and risk models point to age and various co-morbidities. The NCDR CathPCI risk model<sup>108</sup> rates a number of variables with the strongest association with in-hospital mortality, including age and various co-morbid conditions (e.g. chronic lung disease, peripheral artery disease, prior heart failure and cardiogenic shock) common in older and disabled individuals. A Mayo Clinic study<sup>109</sup> developed two risk-prediction models, one for mortality alone and one for all major adverse cardiovascular events, and, as with the NCDR Cath PCI risk model, age and various co-morbid conditions common in Medicare beneficiaries successfully predicted the risk of adverse events during the index hospitalization. Therefore, for these kinds of interventional coronary procedures, there is an increased risk for poor outcomes for Medicare beneficiaries.

**The AHA strongly believes that such procedures should only be performed on Medicare beneficiaries in settings in which immediate rescue is available, including rapid access to on-site cardiac surgery as well as an intensive care unit (ICU) in a hospital.** As noted previously, this concern is even greater because CMS has proposed to weaken the current ASC CfC rules that mandate that there is a plan in place in the event such emergencies arise.

Further, as previously noted, in addition to the inherent risks for Medicare beneficiaries associated with performing these procedures in ASCs, physicians that own ASCs are not subject to the Stark self-referral regulations and so there may be other incentives in place in making a determination of the appropriate site-of-service.

Finally, we note that while CMS suggested safeguards for TKA procedures, there were none suggested for the coronary artery procedures that CMS proposed to include in the ASC list of covered services. While we still have reservations about the safeguards CMS suggested and oppose this policy entirely, if the agency were to finalize it, we would urge it to establish and enforce certain safeguards to protect Medicare beneficiaries. For example, CMS could require that ASCs develop a patient-specific plan of post-operative care for each beneficiary and institute minimum facility

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<sup>108</sup> Peterson ED, Dai D, DeLong ER, et al. Contemporary mortality risk prediction for percutaneous coronary intervention: results from 588,398 procedures in the National Cardiovascular Data Registry. *J Am Coll Cardiol.* 2010;55(18):1923–1932. doi:10.1016/j.jacc.2010.02.005

<sup>109</sup> Kassaian SE, Saroukhani S, Alaeddini F, et al. A Risk-Scoring Model to Predict One-year Major Adverse Cardiac Events after Percutaneous Coronary Intervention. *J Tehran Heart Cent.* 2015;10(4):167–175.



experience requirements for ASCs including minimum annual procedure performance standards for its physicians.

Comment Request on Other Coronary Intervention Procedures. CMS also reviewed several other coronary intervention procedures for possible inclusion in the list of ASC-covered procedures. While it does not believe that these procedures meet Medicare criteria for inclusion on the ASC list at this time, CMS requests comments about whether these procedures can be performed safely in an ASC setting. **The AHA opposes adding these additional procedures to the ASC list for all the same reasons we oppose adding the proposed coronary intervention procedures. We believe that doing so would be unsafe for Medicare beneficiaries and not clinically appropriate in an ASC setting.**

## **COMMENT SOLICITATION ON COST REPORTING, MAINTENANCE OF HOSPITAL CHARGEMASTERS AND RELATED MEDICARE PAYMENT ISSUES**

Hospitals are required to submit to CMS an annual cost report, which typically includes, among other data, charge information derived from the hospital chargemaster. In the proposed rule, CMS requests stakeholder comment on several aspects of the Medicare cost reporting process and use of the chargemaster. Below, we outline a number of considerations for CMS to take into account as the agency examines the relationship between the hospital chargemaster and Medicare cost report. **Given the significant functions of both of these, it is essential that any considerations or activities to modify content or processes associated with these data sources include ongoing stakeholder input, especially opportunities for providers to share their perspectives and first-hand knowledge.**

The Role of the Chargemaster. The hospital chargemaster is the master file, developed within a provider's information system, which contains charges and other information<sup>110</sup> about items and services provided by the hospital. Importantly, Section 1128(b)(6)(A) of the SSA and the Medicare Provider Reimbursement Manual stipulate that hospitals must apply a uniform charge structure across payers. This means that for any one item or service, the chargemaster must have the same charge listed regardless of the department listed, and the same charge must be applied irrespective of payer. Thus, as the main data source for charge information, the chargemaster plays an integral role in hospital financing.

In addition to informing Medicare payment, discussed in more detail below, the chargemaster also can inform negotiated prices. Often, health plan/provider negotiations begin with a basic discount off of charges. From there, however, various

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<sup>110</sup> Typically, the chargemaster includes a description of the item or service, its charge, a reference number, the relevant department, an associated revenue code, and the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code.

types of contract terms — including bundling provisions, volume discounts, and various protection clauses — may be applied, meaning that a final adjudicated claim is only loosely correlated to the initial charge. Moreover, the final adjudicated claim represents the total payment due to the hospital from both the health plan and the patient. The patient's portion is based on her specific benefit package, including cost-sharing obligations and where she is in her deductible and total out-of-pocket spending. Therefore, chargemaster charges do not have a direct relationship to what most patients pay for hospital services.<sup>111</sup>

While hospital charges do not directly determine Medicare reimbursement, charges apply to several types of Medicare payments by way of the cost-to-charge ratio, or CCR. A hospital's CCR reflects the relationship between a hospital's costs and charges (e.g. if a hospital's costs equals \$80 and its charges equal \$100, the hospital's CCR will be 80% or 0.80). For a number of Medicare payments that take costs into consideration, hospital's charges are multiplied by its CCR to determine its costs. Charges originating from the hospital chargemaster, reported to CMS via the Medicare cost report, are reduced to costs and applied to the following components and types of Medicare payments:

- *Relative weights.* Hospitals aggregate their costs into “cost centers” on the Medicare cost report that are associated with charges for the same services. For the IPPS, CMS determines national average CCRs for costs collapsed into 19 different cost centers. It then applies these CCRs to national average hospital charges from claims data to determine average costs and the relative weights by DRG. For the OPSS, hospital costs for relative weights are determined by multiplying hospital charges by the full number of department-specific CCRs. Thus, while the two payment systems vary slightly in approach, charges ultimately inform both inpatient and outpatient PPS payments by contributing to relative weights.
- *Outlier payments.* Outlier payments are designed to limit losses for hospitals treating patients that are significantly more costly than average. For inpatient care, outlier payments are made when the cost of the case exceeds the DRG payment by a certain amount, referred to as the fixed-loss outlier threshold. The outlier payment is equivalent to 80% of the marginal cost of the case. Costs are determined by multiplying the hospital's charges for the case by its CCR from the hospital's most recently available cost report. Outpatient outlier payments follow a similar process. Thus, charges are used in determining whether an inpatient or outpatient case qualifies for outlier payments as well as the amount of outlier payments.

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<sup>111</sup> In limited instances, self-pay patients may be billed the full charge amount. However, hospitals typically apply a discount to the charge for uninsured patients.

- *Pass-Through Payments.* Medicare makes additional payments for cases utilizing eligible new technologies. As finalized in the FY 2020 IPPS final rule, CMS makes new technology add-on payments (NTAPs) at 65% the marginal cost of the case, capped at 65% of the cost of technology itself. Similar to outlier payments, costs are calculated as the product of the hospital's charges and its CCR. Charges are therefore used in determining the amount of NTAPs. Pass-through payments made under the OPSS are analogous to NTAPs although the methodologies for determining payment differ. Implantable devices paid under pass-through are paid using the hospital's charges reduced to cost by applying the hospital's CCR.
- *Medicare Disproportionate Share Hospital (DSH) Uncompensated Care Payments.* Under the DSH program, a funding pool comprising 75% of Medicare DSH funds is distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides. Each hospital's uncompensated care is based on its charity care costs plus bad debt costs. The hospital's CCR is multiplied by the hospital's charges for charity care to determine charity care costs. The CCR also is multiplied by certain bad debt charges to determine bad debt costs.
- *Payment to Cost Ratios for Cancer and Children's Hospitals.* Certain hospitals receive a type of hold harmless payments based on payments as a percent of costs — the payment-to-cost ratio (PCR) — under Medicare's prior reasonable cost system compared to the OPSS. The target PCR for each hospital is determined by comparing the hospital's payments to its costs (calculated as the hospital's charges adjusted by its CCR).

Maintaining the Chargemaster. In light of the chargemaster's role in hospital payments, it is critical to maintain its accuracy. To keep chargemasters up to date, hospitals typically implement updates at least annually to align with key changes in coding, guidelines and regulations. Many hospitals use automated systems to assist in chargemaster management and reduce the potential for errors. In addition to an annual update, some hospital departments may modify their related items and services more frequently, such as quarterly updates to check for coding errors and/or to make updates for new or eliminated items/services. Some departments conduct periodic internal audits of their chargemaster items and services for quality assurance. Moreover, some service lines, such as pharmacy, may have regular chargemaster data "refreshes" to capture changes in the costs of those items to the provider (e.g., vendor price changes, volume changes).

Hospitals dedicate substantial attention and resources to the upkeep of their chargemaster, reflecting its fundamental nature in hospital activities. This master file may contain hundreds of thousands of line items and require significant coordination between departments. While resources dedicated to the chargemaster vary by hospital, some devote more than 10 FTEs to chargemaster management. In addition to

employee support, many hospitals also purchase software tools to aid in maintaining the chargemaster.

The Medicare Cost Report. The Medicare cost report is a rich data source for understanding hospital finances, determining Medicare reimbursements, and informing certain payment decisions outside of the Medicare program. Hospitals and most other entities that participate in Medicare are required to submit a cost report on an annual basis. Completing the cost report requires particular expertise. The cost report includes information about the facility, service utilization, wages, costs and charges, in addition to other statistical and financial data. These data are captured in numerous series of worksheets. There are more than 10 series that may apply to hospitals, and each series comprises numerous worksheets. (For example, the Worksheet S series contains 10 different individual worksheets, with some having multiple parts.) Worksheets often have interrelated information: certain lines of data in a particular worksheet may be part of calculations elsewhere. As a result, seemingly small technical changes may ultimately have material impact.

The Medicare cost report plays an essential role in determining many types of Medicare reimbursements. As noted above, charges from a hospital's chargemaster are documented in the cost report to derive the CCRs across cost centers, which are then used to calculate national CCRs and ultimately determine relative weights. The cost report also contains the charge and cost information that is considered when determining outlier payments, pass-through payments, and uncompensated care payments. In addition, facilities that are reimbursed outside of the Medicare PPS, such as CAHs and PPS-exempt cancer hospitals, rely on the cost report to submit data needed for their unique cost-based reimbursement structures. As such, any modifications to the cost report would have a variable impact on different types of payments and providers.

In some states, the Medicare cost report also is used in calculating Medicaid payments. A number of state Medicaid programs rely on the cost report to set prospective payment rates and/or determine supplemental payments. For example, data from the cost report is used by some state Medicaid programs to calculate DRG weights and base payments, calculate outlier payments, set per diem rates or determine cost-based payments for non-DRG hospitals, and calculate hospital upper payment limits for supplemental payments. Thus, changes to the cost report may have impacts outside of the Medicare program.

Given the widespread utilization of the cost report, we appreciate CMS's interest in streamlining the process. We believe that a well-functioning cost reporting system is characterized by accurate, timely and meaningful information that does not entail undue burden. In addition, improvements made to the cost report itself should be accompanied by efforts to improve instructions and streamline related processes including report review and finalization, audits, appeals and settlements. Therefore, it is essential that any efforts toward cost report reform are done with ongoing input from and collaboration

with providers, who have direct experience with cost report data collection, submissions and post-submission activities. The hospital field is well-equipped to identify opportunities for improvement, as well as potential drawbacks of proposed changes (e.g., eliminating data elements that are utilized for a Medicaid-related calculation as described above).

One example of such input would be a Medicare Technical Advisory Group (MTAG) focused on the cost report. MTAGs have been used in the past to tackle similarly complex issues and processes, and provide a forum for critical stakeholder engagement. We believe that this approach would be necessary in light of the technical nature of the cost report, the interconnectedness among cost report lines and worksheets, and the importance of considering unintended consequences of any cost report changes in light of its use for non-PPS hospitals and for Medicaid payments in some states.

## **REQUEST FOR INFORMATION ON QUALITY TRANSPARENCY RELATING TO PRICE TRANSPARENCY**

The proposed rule includes an RFI soliciting feedback on how the agency could combine information on provider quality performance with prices. CMS suggests that in prior RFIs, some stakeholders have suggested that combining relevant quality information with pricing information would augment patients' ability to "shop" for services.

As longstanding supporters of quality transparency, America's hospitals and health systems believe that patients, families and communities should have valid, clear and important quality information to help them make important health care decisions. In fact, a voluntary effort led by hospitals ultimately led to CMS's creation of the *Hospital Compare* website that has been the backbone of the agency's quality transparency efforts for over a decade. Thus, in concept, the AHA agrees that patients should have a combination of both quality and out-of-pocket cost data available to them to inform their care decisions. **However, the AHA strongly urges CMS to view all requirements to report quality data — regardless of whether such requirements relate to the agency's price transparency efforts — as part of its broader quality strategy. New quality measurement and reporting requirements should advance the agency's concrete quality priorities, and not simply serve the agency's price transparency agenda.**

**Indeed, the AHA is concerned that quality measurement requirements that are too narrowly focused on the agency's price transparency agenda could hamper the agency's progress on using "meaningful measures" in programs.** For too long, the measures in CMS programs proliferated without a tie to concrete quality priority areas. When the measures in programs are too numerous, data collection activities can overwhelm hospital staff and limit their ability to do what matters most — improving

care. Furthermore, excessive measurement requirements come at a substantial cost. The AHA's 2017 *Regulatory Overload* report found that an average community hospital spends over \$700,000 per year just to meet CMS's quality measurement requirements. This amount does not include the substantial reporting requirements hospitals often face from private payers, state agencies and others. For these reasons, the AHA has strongly supported CMS's Meaningful Measures initiative that has resulted in an approximately 30% reduction in the number of measures used in its hospital programs. As CMS considers what measures it might use in the context of its price transparency agenda, we strongly urge it ensure any new requirements are aligned with its Meaningful Measures framework.

Informed by this perspective, we offer suggestions on two specific RFI questions:

- Should CMS display information about the volume and complications of procedures side-by-side with charge information? **While procedural volume can be helpful contextual information, the AHA has a number of concerns about its use as quality metric.** There remains no definitive research about the marginal volume of procedures at which patient outcomes will improve significantly. As a result, any prescribed number of procedures against which a hospital is measured likely would be arbitrary. Furthermore, the use of volume alongside out-of-pocket cost information may inadvertently signal that volume is the most important indicator of procedural safety. In fact, the factors influencing procedural safety go much deeper. Hospitals and surgeons routinely engage in a variety of strategies — such as simulation training, operative time outs, improved safety culture, process improvement techniques — to enhance the safety and quality of procedures.

The results of this hard work are reflected in more sophisticated quality measures in CMS programs, such as infection rates and readmissions. These measures can be thought of as “complication” measures, and sometimes, it makes sense to calculate them on a procedure-by-procedure basis. However, it often is more appropriate to use a broader patient population to ensure adequate measure reliability.

- Should CMS's Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey should include questions about how well hospitals communicate cost of care information with patients? **The AHA believes an HCAHPS measure about communication on costs likely is infeasible and of limited value to provider improvement efforts and transparency for patients.** As noted elsewhere in this letter, there are a number of operational challenges associated with providing patients with out-of-pocket cost information. As a practical matter, it would be difficult to ensure that the timeframes of HCAHPS survey administration and the issuance of information about out-of-pocket costs would match up. HCAHPS surveys are sent to patients from 48 hours to up to six weeks following hospital discharge. It is possible that full

information about out-of-pocket costs would be available to patients before an HCAHPS survey is sent, but depending on the case, the survey may go out sooner.

Furthermore, we do not understand what the agency means by “how well” the information is communicated. Does it mean an out-of-pocket estimate was generated at all? That the out-of-pocket estimate matches what patients actually pay? That the information was provided in a usable format? The field as a whole continues to learn the best approaches to communicating information that is meaningful to patients, and it seems premature to develop a measure around practices that continue to evolve.

## **PROPOSED CHANGES TO GRANDFATHERED CHILDREN'S HOSPITALS-WITHIN-HOSPITALS**

CMS proposes to allow grandfathered children’s HwHs to add beds without losing grandfathered status. **The AHA urges adoption of this proposed change as an important step to ensure greater access to appropriate care for children.**

CMS defines a HwH as a hospital that occupies space in the same building or on the same campus as another hospital. In the fall of 1995, CMS established requirements that a HwH would have to be meet to be considered a separately certified hospital. A HwH in existence on or before Sept. 30, 1995 is excluded from those requirements as long as it continues to operate under the same terms and conditions, including the same number of beds.

The decision to co-locate hospitals on the same campus or in the same building is made to facilitate effective, patient-centered and coordinated clinical care. Such arrangements not only lead to better patient care in many communities, they result in decreased burden for patients, increased coordination of care, particularly for complex patients, and excellent opportunities for training medical students, residents, nursing students and other health professionals.

A hospitals within another hospital and under the grandfather clause has been unable to expand its bed size since 1995, despite advances in science that created more treatment options for children, the emergence of new diseases and disorders and any growth in the population served. Because medical knowledge is expanding rapidly, and new treatments and technologies are critical to improving patient outcomes, CMS’s proposed change eliminates a restriction imposed on some children’s hospitals that put them at a disadvantage not experienced by other children’s hospitals, and thus will create a fairer opportunity for all children’s hospitals to change with the needs of the communities they serve.

AHA applauds CMS for taking this step and fully supports the proposed change.

## **CLINICAL LABORATORY FEE SCHEDULE: POTENTIAL REVISIONS TO THE LABORATORY DATE OF SERVICE POLICY**

Many hospitals do not perform in-house the more technologically advanced laboratory tests, such as molecular pathology and advanced diagnostic laboratory tests (ADLTs), which use specimens collected from hospital outpatients. Rather, upon receipt of a physician's orders, hospitals often send patient specimens to independent laboratories for testing. In the CY 2018 OPSS/ASC final regulation, in response to concerns that the laboratory date-of-service (DOS) policy, referred to as the "14-day rule," was administratively burdensome for hospitals and for the independent laboratories that furnish these tests and that it created delays and other barriers to patient access to critical diagnostic testing, CMS established an exception. This exception was intended to enable independent laboratories performing certain ADLTs and molecular pathology tests excluded from the OPSS laboratory test packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital. The exception establishes that the DOS for molecular pathology tests and certain ADLTs is the date the test was performed only if:

- the test was performed following a hospital outpatient's discharge from the HOPD;
- the specimen was collected from a hospital outpatient during an encounter;
- it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- the results of the test do not guide treatment provided during the hospital outpatient encounter; and
- the test was reasonable and medically necessary for the treatment of an illness.

When all conditions under the exception are met, the independent laboratory performing the test bills Medicare directly for the test under the CLFS.

After this policy was finalized, CMS heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing this DOS exception and, as a result, CMS delayed enforcement of the policy several times, ultimately delaying it until Jan. 2, 2020.

Potential Revisions to Laboratory DOS Policy. In response to the implementation concerns, CMS is considering making additional changes to the exception, by changing the test results requirement and/or limiting the DOS exception to certain ADLTs (thereby excluding molecular pathology tests from this exception). **The AHA is concerned that CMS's potential changes to the lab test DOS exception would not address the administrative difficulties that hospitals and independent laboratories experienced with the current exception and could negatively affect patient access to advanced testing and treatments. We recommend that CMS not finalize either of these potential changes to the laboratory DOS exception.**



*Changing the Test Result Requirement.* One of the current factors required to qualify for the DOS exception is that the results of the test must not guide treatment provided during the hospital outpatient encounter in which the specimen was collected. Under the current regulation, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during the hospital outpatient encounter.

CMS is considering revising the policy to specify that, if the ordering physician determines that the test results are not intended to guide treatment during the hospital outpatient encounter from which the specimen was collected *or during a future hospital outpatient encounter*, the DOS service of the test would be the date of test performance. In this situation, the test would not be considered a hospital service and the performing independent laboratory would be required to bill for the test.

**The AHA urges CMS not to finalize this change in the test result requirement.** This potential change simply would not work. The ordering physician would have no way of knowing the settings in which the patient's future care would be furnished at the time the specimen is collected during the original hospital outpatient encounter. If the ordering physician is uncertain about the next site of service, would the DOS default to the date that the specimen was collected (requiring the hospital to bill for the test) or the date that the laboratory test was performed (requiring the independent laboratory to bill for the test)? Given this uncertainty, any decision made by the ordering physician could be incorrect, putting the physician, hospital and performing laboratory at risk for noncompliance. Attempting to correct such errors retroactively, such as by the hospital filing an adjustment claim, would be administratively burdensome and costly.

In addition, because the molecular pathology tests and the ADLTs to which the DOS exception applies are billed separately under the CLFS, regardless of which provider performs the test, the Medicare payment system and the payment amount are not affected by this potential change to the current DOS exception. There simply is no benefit to this misguided potential change. It is all burden and no benefit. Given CMS's focus on reducing administrative and regulatory burden and prioritizing patients over paperwork, we urge CMS not to finalize this unnecessary and burdensome policy.

*Limiting the Laboratory DOS Exception to ADLTs.* Part of the reason that CMS established the laboratory DOS policy exception in the CY 2018 OPSS final rule was due to concerns that the previous policy created beneficiary access issues with regard to molecular pathology tests and ADLTs. CMS included molecular pathology tests in the exception because it acknowledged that hospitals may not have the technical expertise or certification requirements necessary to perform molecular pathology testing and therefore must rely on independent laboratories to perform these tests.

However, in the CY 2020 proposed rule, CMS states that it no longer believes that the same beneficiary access concerns which apply to ADLTs also apply to molecular

pathology tests. That is, unlike ADLTs, molecular pathology tests are not required by law to be furnished by a single laboratory, and so CMS claims that hospitals are not prevented from performing molecular pathology testing. The agency further notes that FDA has approved a number of kits that would allow a hospital to more easily perform some of these molecular pathology tests. CMS also believes that a hospital's laboratory can develop the expertise to perform a molecular pathology test or establish an arrangement with an independent laboratory to perform the test. Thus, the agency now believes that any incentives that may exist to delay ordering until at least 14 days following a patient's discharge from the HOPD (i.e. the 14-day test DOS rule) do not apply to molecular pathology tests. Therefore, CMS is considering a potential revision that would limit the laboratory DOS exception provisions to tests designated by CMS as an ADLT. Molecular pathology tests would be removed from the exception provisions.

**CMS is incorrect in its assumptions that there have been significant changes in the last two years in the factors that led it to conclude in the 2018 final rule that the patient access concerns apply to both molecular pathology tests as well as ADLTs. Therefore, we urge CMS not to exclude molecular pathology tests from the DOS exception.**

Just because molecular pathology tests are not required by statute to be furnished by a single laboratory does not mean that hospitals are able to offer the full range on molecular pathology tests that are of clinical benefit to their patients. While hospital laboratories can develop the expertise to perform certain molecular pathology tests, there are other highly specialized or technically sophisticated tests that may only benefit a small patient population. In these cases hospital laboratories may not be able to justify the costs of investing in these testing systems. That is why this DOS exception was created in 2018.

In addition, while there may now be greater availability of FDA-approved kits for molecular pathology testing, many hospitals would not have the capability to perform such specialized testing and the cost of bringing this specialized testing capability in-house may be prohibitive for many hospitals, particularly if the volume of testing is expected to be low. This would particularly be the case for smaller and rural hospitals.

We also believe that CMS is incorrect in its assumption "that any incentives that may exist to delay ordering until at least 14 days following a patient's discharge from the HOPD do not apply to molecular pathology tests." If the DOS exception is changed to exclude molecular pathology tests that hospitals don't offer in-house or under arrangements, then once again, specimen collection and test performance timing will have to comply with the requirements of the 14-day rule, which can interfere with timely patient care.