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October 5, 2020

The Honorable 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–1736–P, Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (Vol. 85, No. 156), August 12, 2020.

Dear Administrator 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) 2021.

Below is a summary of our overarching concerns and comments:

340B Drug Pricing Program. **The AHA continues its steadfast opposition to any payment cuts made to 340B hospitals. We do not believe HHS has the legal authority to punitively target 340B hospitals in this manner.** Since 2017, HHS has proposed yearly Medicare OPPS payment cuts for drugs purchased under the 340B program at a rate of Average Sales Price (ASP) minus 22.5% from the original payment rate of ASP plus 6%, representing an almost 30% payment cut. This policy eliminated approximately $1.6 billion annually in payments to hospitals participating in the 340B program. In the CY 2021 OPPS proposed rule, HHS proposes a new payment rate, further reducing the payment for drugs purchased under the 340B program to ASP

minus 28.7%. This proposal is estimated to take an additional $427 million from 340B hospitals and builds on flawed policy that has already resulted in devastating losses to 340B hospitals and their patients. **To this point, the AHA, along with other hospital associations and member hospitals, recently called on the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the July 31 non-unanimous decision by a three-judge panel that upheld the authority of HHS to cut 2018 and 2019 Medicare OPPS payments for 340B hospitals by nearly 30% per year. As 340B hospitals rise to meet the tremendous challenges resulting from the COVID-19 pandemic, the AHA asks HHS to immediately reverse this harmful policy and ensure these hospitals can continue to provide vital services to the patients and communities they serve.**

Inpatient-only List. **With regard to CMS's proposed changes to the inpatient-only (IPO) list, the AHA opposes eliminating the IPO list over a three-year period.** Given the depth and breadth of the more than 1,700 procedures on the IPO list, it would be premature and myopic to adopt such a policy. The IPO list was put into place to protect beneficiaries; many of its services are surgical and high risk. They are complicated and invasive procedures with the potential for multiple days in the hospital, an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. In addition, we are concerned about the financial and administrative burden of the elimination of IPO list at the same time that hospitals are grappling with the COVID-19 pandemic. It would be unconscionable to finalize this policy when the financial impact of the COVID-19 public health emergency (PHE) has already been devastating for hospitals – and there still remains an uncertain future as to the path of the pandemic. **We recommend that CMS continue with its standard process for removing procedures from the IPO list. The agency could enhance determinations about individual procedures that could be safely removed by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities and social support, and other factors relevant to positive patient outcomes.**

ASC Covered Procedures List. **The AHA strongly opposes both of CMS's alternative proposals regarding the ASC covered procedures list (CPL). They would substantially weaken the agency's process and regulatory exclusion criteria for determining whether surgical procedures may be added to the ASC-CPL. Both alternatives would result in far more and higher risk surgical procedures being covered; the AHA is concerned that this could negatively impact Medicare beneficiary safety and quality of care.** As has been demonstrated in recent years, the existing ASC regulatory criteria have supported the ability of ASCs to safely furnish an expanding range of surgical procedures as innovations in surgical care occur. However, because ASCs are not subject to the same level of regulatory oversight as hospitals and are not equipped to manage emergencies that require lifesaving hospital inpatient capabilities, keeping the ASC general exclusion criteria in place psrevent surgical procedures that pose significant threats to beneficiary safety

and quality of care from being performed in ASCs. **In addition, the AHA strongly opposes CMS's proposal, under Alternative 2, to add 270 surgery or surgery-like codes to the ASC-CPL that it believes would meet the proposed revised criteria for 2021.** CMS did not provide any rationale that these procedures meet even the general regulatory standards for adding ASC-covered surgical procedures. **Furthermore, although the AHA strongly opposes the proposed changes to the ASC-CPL process and criteria, if CMS were to nevertheless finalize either alternative, we urge the agency to work with clinical experts and other stakeholders to make appropriate changes to the ASC Conditions for Coverage (CfC) in response to the expanded range of higher risk services that would be covered in the ASC setting. Particularly, we recommend restoring the CfC requirements removed in 2019 requiring written hospital transfer agreements or physician admitting privileges at a hospital.**

Hospital Overall Star Ratings. **The AHA applauds CMS for proposing changes to hospital overall star ratings.** The changes attempt to address the serious questions AHA and others have raised about the transparency and fairness of the ratings. We strongly urge CMS to adopt its proposals to discontinue the use of the latent variable modeling approach to measure group scores, and to stratify hospital readmissions measure group scores by the proportion of dual-eligible patients. We also agree with the intent behind CMS's proposal to peer group hospitals by the number of reported measure groups, though we encourage the agency to continue exploring additional alternative approaches.

Physician-owned Hospitals. **The AHA strongly opposes CMS's proposals to remove certain restrictions on the expansion of physician-owned hospitals (POHs) that qualify as high-Medicaid facilities.** These proposals would significantly undermine the statutory provisions in the Stark law and Affordable Care Act that protect federal health care programs from the inherent conflict of interest created when physicians self-refer their patients. Such a change flouts decades of evidence, including from as recently as August, that POHs cherry-pick healthy patients, provide few emergency services or uncompensated care, and are penalized for unnecessary readmissions at 10 times the rate of non-POHs, all while maintaining significantly higher operating margins than non-POHs. In fact, CMS's proposals to ease expansion for high-Medicaid facility POHs would allow expansion of facilities that actually have extremely low-Medicaid discharge percentages when compared with hospitals in surrounding counties. **These proposals pose grave risk to the stability and integrity of patient care and should not be finalized.**

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

- Recommends that CMS reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted provider-based departments;
- Recommends that CMS revise the medical review exemption policy for services removed from the IPO list. Doing so would provide ongoing deference to the physician's judgement about the appropriate site of care, and thereby exempt

providers from site-of-service claims denials until there is evidence showing that a removed service is more commonly performed on an outpatient basis.
- Strongly supports CMS's proposal to permanently establish general supervision as the minimum required supervision level for all non-surgical extended duration therapeutic services;
- Supports CMS's proposal that direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services could include the virtual presence of the physician through audio/video real-time communications technology. However, we urge CMS not to finalize a clarification that would require the physician's "real-time presence throughout the performance of the procedure," rather than "immediate availability" using this technology;
- Urges CMS to continue the "Hospital without Walls" flexibilities to the greatest extent possible; and
- Continues to oppose the OPPS prior authorization program, as well as its expansion to two new categories of service, as the policy is contrary to law and arbitrary and capricious.

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.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

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) 2021

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OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

For CY 2019, citing "unnecessary" increases in the volume of outpatient clinic visits in hospital provider-based departments (PBDs) allegedly due to payment differentials driving the site-of-service decision, CMS finalized a policy to pay for clinic visits furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. Specifically, in the CY 2019 final rule, CMS adopted a policy to pay for excepted clinic visit services at the physician fee schedule (PFS)-equivalent payment rate of 40% of the OPPS payment amount. The agency, however, phased-in the application of this policy over two years. That is, in CY 2019, half of the reduction was applied, meaning that in 2019, excepted off-campus PBDs are paid 70% of the OPPS rate for excepted off-campus clinic visits services and in CY 2020, CMS completed the phase-in to pay for clinic visit services furnished in excepted off-campus PBDs at the payment rate of 40% of the OPPS payment amount. This policy was implemented in a non-budget neutral manner, which the agency estimated would result in a CY 2020 reduction of $800 million in hospital payments under the OPPS.

For CY 2021, CMS would continue to pay for the hospital outpatient clinic visit services in off-campus excepted PBDs at 40% of the OPPS payment amount. **AHA continues to believe that the payment cut for hospital outpatient clinic visits threatens access to care, especially in rural and other vulnerable communities, and that CMS has undermined clear congressional intent and exceeded its legal authority.** The AHA is seeking a rehearing by the full U.S. Court of Appeals for the District of Columbia Circuit of the recent decision overturning a lower court's ruling in favor of AHA and hospitals that invalidated HHS's policy finalized in the CY 2019 rule to pay for clinic visit services in excepted PBDs at the "PFS-equivalent" payment rate of 40% of the OPPS payment amount. For further discussion on this topic, please see the AHA's CY 2020 OPPS/ASC proposed rule comment letter and the AHA's Petition for Panel Rehearing or Rehearing En Banc.

The Growth in Outpatient Volume and Expenditures is not "Unnecessary". **This policy not only runs afoul of the law but also relies on the most cursory of analyses and policy rationales.** In its CY 2019 and 2020 rulemaking, CMS finalized its phased-in policy implementing a 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 OPPS 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 OPPS 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 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 OPPS 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. 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, such as:

- Readmissions program;
- Value-based care;
- Two-midnight policy;
- Packaging of clinical laboratory services into the OPPS; and
- Changes to the inpatient-only (IPO) list.

Factors Outside of Hospitals' Control that Increase OPPS Volume and Expenditures. There are many broader health care trends that contribute to the increase in OPPS 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 cannot be considered "unnecessary," although CMS did not attempt to analyze their effect.

- Drug Price Inflation. In the CY 2019 OPPS proposed rule, CMS included a table which described the growth in expenditures under OPPS from CY 2010 through CY 2019. The agency used these data to justify its proposed policy intended to address "unnecessary" growth in volume in the OPPS. 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 OPPS expenditures that is entirely outside of the control of hospitals. Indeed, HHS, the Medicare Payment Advisory Commission (MedPAC) and others have expressed concern about the rapid growth in drug expenditures. According to MedPAC, "The largest source of OPPS spending growth has been Part B drugs, which include those that have pass-through status (drugs that are new to the market) and those that are not pass-through but are separately payable under the OPPS. From 2012 to 2018, OPPS spending for these drugs increased from $6.0 billion to $12.9 billion, an increase of 115% (13.6% per year, on average) … The growth in spending on Part B drugs is due to price increases, increased use of existing drugs, and, to a lesser extent, the introduction of new, expensive cancer drugs."[1]

  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%).[2] This growth was driven primarily by changes in drug prices, including both higher launch prices and annual price increases, not utilization.[3] In recent years, growth in spending on prescription drugs has slowed from those historic levels, yet the impact of continued price increases is compounded by the simple fact that each annual increase builds on the previous year's increase. For example, in 2017 increases continued for drugs like mitomycin, which is used to treat cancer, and hydromorphone, an injectable opioid. Mitomycin nearly doubled, increasing by 99 percent, and hydromorphone increased by 107 percent. As prices have continued to increase for many drugs like mitomycin, ongoing manufacturing shortages of many prescription drugs have threatened patient access to care.[4]

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

Continued Cuts to Hospital Reimbursements for Clinic Visits are Excessive and Harmful, Especially during the Global COVID-19 Pandemic. As noted above, CMS

[1] MedPAC Report to the Congress: Medicare Payment Policy, March 2020.
[2] The National Health Expenditure Accounts.
[3] U.S. Department of Labor, U.S. Bureau of Labor Statistics. PPI Detailed Report: December 2017.
[4] NORC at the University of Chicago, "Recent Trends in Hospital Drug Spending and Manufacturer Shortages", Jan. 1, 2019.

proposes to continue to impose the 60% cut in payment for clinic visits furnished in excepted off-campus PBDs. **Continuing these cuts to outpatient payment for clinic visits, particularly in light of the devastating impact that the COVID-19 pandemic has had on hospital and health system financial health, would be excessive and harmful to patients and communities.**

Hospitals and health systems are expected to lose a minimum of $120.5 billion from July through December 2020 as a result of the pandemic, due in large part to lower patient volumes, according to an AHA report.[5] This is an average of $20.1 billion per month. These estimates are in addition to the $202.6 billion in losses the AHA estimated hospitals incurred from March through June 2020[6]. This brings the total estimated pandemic-related losses for the nation's hospitals and health systems to at least $323.1 billion in 2020. While, to date, the impact of COVID-19 has been significant, even with federal emergency funding, the financial damage is likely to continue. Adding to this financial impact is the unpredictability of COVID-19's trajectory, and the pace and degree of patients' return to hospitals. In the face of greatly eroded volume and revenue, and a long recovery period, many hospitals are confronted with extremely difficult choices about their paths forward as vital community assets. Now more than ever, hospitals will need support from government for what is likely to be a highly challenging environment even as COVID-19 cases diminish.

Continuing to impose a 60% cut on clinic visit services in 2021, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID-19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.

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 1.7 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.3 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.[7]

[5] https://www.aha.org/system/files/media/file/2020/06/aha-covid19-financial-impact-report.pdf.
[6] https://www.aha.org/system/files/media/file/2020/05/aha-covid19-financial-impact-0520-FINAL.pdf.
[7] Source: KNG Health Consulting, LLC analysis of 2011-2019 Medicare Inpatient, Outpatient, and Carrier Standard Analytical Files and Denominator files.

Among Medicare beneficiaries with cancer, the differences in the types of patients seen in HOPDs compared to physician offices is even starker. For example, 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 2.2 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.8 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.[8]

Further, according to the FY 2018 Medicare cost report data, Medicare margins for outpatient services were negative 13.8% in 2018. Overall Medicare margins were negative 9.3% in 2018, with a negative 11% margin predicted for 2019.[9,10] Of note, even "efficient" hospitals had a margin of negative 2% in 2018, according to MedPAC.[11] **The site-neutral payment policies implemented by CMS for 2018 and beyond will reduce these margins further. Moreover, according to a recent analysis of the impact of the COVID-19 pandemic on hospitals, prepared by Kaufman, Hall & Associates LLC[12] and released by AHA, even with the Coronavirus Aid, Relief, and Economic Security (CARES) Act funding, hospital operating margins are expected to drop 5.5 percentage points – to negative 2% in the second quarter of 2020.** Before COVID-19, the median hospital operating margin was a modest 3.5%. For any organization, a positive operating margin is essential for long-term survival.

We are concerned that continued Medicare site-neutral payment reductions, together with the devastating impacts of COVID-19, 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.**

In fact, this erosion 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, 132 rural hospitals have closed since 2010, 15 of them in 2020 thus far. 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

[8] Ibid.
[9] MedPAC Report to the Congress: Medicare Payment Policy. March 2020.
[10] MedPAC Report to the Congress: Medicare Payment Policy. March 2019.
[11] MedPAC Report to the Congress: Medicare Payment Policy. March 2020.
[12] https://www.aha.org/system/files/media/file/2020/07/KH-COVID-Hospital-Financial-Health_FINAL.pdf.

mine." They serve as the initial indicators that we are beginning to reach a tipping point where private payers are no longer willing to fund, and hospitals can no longer sustain, operations on the cost-shift that such considerable Medicare underpayments, particularly those under OPPS, necessitate.

Site-neutral Policies are Based on Flawed Assumptions. Finally, the entire premise of CMS's site-neutral policies is 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 discussion supports the conclusion that CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted PBDs.

PAYMENTS FOR 340B

HHS, through CMS, has relentlessly pursued payment policies designed to undermine the scope and intent of the 340B Drug Pricing Program. Since 2017, HHS has proposed yearly Medicare OPPS payment cuts for drugs purchased under the 340B program at a rate of Average Sales Price (ASP) minus 22.5%, representing an almost 30% payment cut from the original payment rate of ASP plus 6%. This policy eliminated approximately $1.6 billion annually in payments to most hospitals participating in the 340B program.

For more than 25 years, the 340B program has been critical for hospitals to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Hospitals rely on these savings to provide important services and resources that they may otherwise be unable to provide, many of which are targeted to low-income and otherwise vulnerable communities. These savings have proved especially important as 340B hospitals are also on the front lines of the COVID-19 PHE. We, therefore, continue to argue, as documented in our court filings, that HHS does not have the legal authority to punitively target 340B hospitals in this manner. **On Sept. 14, the AHA, Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs called on the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the July 31 non-unanimous decision by a three-judge panel that upheld the authority of HHS to cut 2018 and 2019 Medicare OPPS payments for 340B hospitals by nearly 30% per year.[13]**

[13] AHA et al vs Azar USCA Case #19-5048 Document #1861298 (US Court of Appeals for the District of Columbia) https://www.aha.org/legal-documents/2020-09-14-hospital-groups-petition-rehearing-re-340-b-payment-reductions-sept-14.

In this CY 2021 OPPS proposed rule, HHS proposes to further reduce payments for drugs purchased under the 340B program to ASP minus 28.7%. This proposal is estimated to cut an additional $427 million from 340B hospitals. HHS is basing this new payment rate on results from CMS's Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs, which was inadequate and incomplete. In addition, the new proposal continues to build on flawed policy that has already resulted in devastating losses to 340B hospitals and their patients. **Therefore, the AHA continues its unshakeable opposition to any payment cuts made to 340B hospitals and asks HHS to immediately reverse this harmful policy and ensure these hospitals can continue to provide vital services for the patients and communities they serve.**

340B Payment Rate Approaches. HHS, in this proposed rule, puts forward a new approach to pay certain 340B hospitals for covered outpatient drugs purchased through the 340B program. That new approach would result in a net payment rate of ASP minus 28.7%.[14] Alternatively, HHS offers to continue the current payment rate of ASP minus 22.5% for 340B hospitals. The department requests comment on retaining the current payment policy in light of the July 31 favorable Appeals Court decision upholding the departments' authority to cut 340B hospitals by nearly 30% annually.[15] However, this choice that HHS has offered to 340B hospitals is a classic Cornelian Dilemma, wherein hospitals are being asked to choose between two courses of action, both of which will have a detrimental effect.[16] **For 340B hospitals, there can be no other choice but for HHS to reverse this harmful and punitive policy. Therefore, the AHA opposes ANY AND ALL proposals that seek to reduce payment to 340B hospitals.**

HHS bases the new proposed payment rate of ASP minus 28.7% on the results of CMS's Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs, which was issued in the spring of 2020. It is important to note that the survey was issued during the height of the COVID-19 PHE while 340B hospitals were struggling to marshal critical resources to respond to the pandemic. All hospitals that are paid under the OPPS and participate in the 340B program were surveyed, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment). A central point in the litigation that AHA and others have brought forth is HHS's failure to collect the required actual acquisition cost data to establish a 340B-specific payment rate. As noted by the Circuit Judge Pillard of the Appeals Court of the District of Columbia Circuit, HHS can only pursue a different payment policy for a distinct hospital group through the robust, hospital-specific data effort specified by the law.[17] Further, the

[14] CMS arrived at the net payment rate of ASP minus 28.7 % by starting at ASP minus 34.7%, plus an add-on of 6% of the product's ASP, for a net payment rate of ASP minus 28.7%. This proposed new payment rate extends to 340B-acquired drugs furnished in non-grandfathered (non-excepted) off-campus provider-based departments and applies to biosimilar drugs and other drugs without an ASP purchased through the 340B program.

[15] https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf.

[16] *Le Cid,* Pierre Corneille, 1637, performed at the Theatre du Marias, Paris.

[17] https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf.

statute requires any such survey to contain a large sample of hospitals that would yield statistically significant data. **HHS's data collection effort falls short of these standards set forth by Congress in several ways.**

First, as AHA noted in our March comments to HHS on the survey, the survey design and approach did not meet the statutory requirements when it specified that only 340B hospitals were required to complete the survey.[18] It is worth repeating that under the statute, in establishing reimbursement rates for outpatient drugs, HHS must either use average acquisition costs based on a survey that meets the requirements of the statute (subclause I of section 1395l(t)(14)(iii)) or average price based on various statutory provisions (subclause II of section 1395l(t)(14)(iii)). HHS may not use subclause I for some hospitals and subclause II for others, and thus it may not limit the survey to a subset of hospitals. Congress in (t)(14)(C)(ii) of the statute directs HHS to collect "hospital acquisition cost for each specified covered outpatient drug for use in setting the payments rates…." Nowhere in the statute does Congress give HHS the authority to collect acquisition cost data from only a specific subset of all hospitals. While Congress does state in (t)(14)(A)(iii) that CMS could vary hospital OPPS payment by hospital group – based on the data gleaned from the hospital acquisition cost survey – the potential variation is premised on the use of the authority in subclause I to establish the rate for all hospitals and thus the survey must include all hospitals, not just a subset of hospitals. In other words, for purposes of surveying hospitals, Congress did not distinguish between hospitals paid under OPPS based on their 340B status and those that are not and doing so is, therefore, a clear violation of the statute.

Second, the statute governing the provision of such a survey requires that the survey data meet certain requirements. Under 42 U.S.C. Sec.1395l(t)(14)(D)(iii), the survey must "…have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."[19] HHS noted only 7% of hospitals that received the survey responded with actual acquisition cost data. Of the remaining hospitals surveyed, 38% did not respond and an additional 55% opted for a "quick survey" where CMS used 340B ceiling prices maintained by the Health Resources and Service Administration (HRSA) as a proxy for actual drug acquisition costs. With such a low response rate, it is apparent that HHS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug. Further, the acquisition data collected in the survey only reflected data from the fourth quarter of 2018 and the first quarter of 2019. Given that drug acquisition costs can vary significantly quarter to quarter due to rapid fluctuations in drug prices, the limited data used to set payment rates may not represent actual acquisition costs in a meaningful way. This could result in a scenario where a drug increases significantly in price, where the payment rate for that drug is below the 340B ceiling price, such that a hospital would incur losses for use of that drug. Ultimately, it is clear that HHS did not meet the basic

[18] https://www.aha.org/system/files/media/file/2020/03/cms-survey-hospitals-participate-340b-drug-pricing-program-3-9-2020.pdf.
[19] https://www.law.cornell.edu/uscode/text/42/1395l.

statutory requirements for use of such a survey in setting payment rates, as outlined above.

Finally, in the proposed rule, HHS noted that it was neither necessary nor appropriate to burden non-340B hospitals with a drug acquisition cost survey because it believed that ASP plus 6% is a reasonable proxy for hospital acquisition and overhead costs for separately payable drugs. However, as Judge Pillard further notes in her dissenting opinion, "But concerns about the program's effects, and confidence in the agency's care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not."[20] **For the reasons outlined above, the AHA strongly believes that HHS's survey used to develop this new payment approach does not meet the statutory requirements and may not be relied upon in establishing the payment rate.**

Failure to Provide Sufficient Analysis for the Continuation of the 340B Payment Policy. In addition to the concerns cited above, HHS has failed to provide any level of transparency or sufficient access to data, methodology or analysis to allow the public to assess and replicate the proposed CY 2021 340B payment policy. AHA has raised similar concerns in prior proposed OPPS payment rules.[21] In fact, there has been no indication that CMS has taken into account changes in which hospitals are actively participating in the program or changes in utilization and volume since CMS first proposed changes to 340B payment policy in 2017. In addition, it appears that CMS did not conduct any analysis of the impact of the prior year reimbursement changes for the drugs acquired under the 340B program for the affected hospitals as it prepared the CY 2021 OPPS proposed rule. Although HHS finalized the 340B policy as budget neutral in prior years, the agency has provided no evidence in the CY 2021 proposed rule that it met budget neutrality requirements. No other conclusion can be made except that HHS did not accurately and effectively ensure the budget neutrality of this policy. **On this point, the AHA recommends that, if HHS is allowed to continue the 340B payment policy, it should annually ensure that it remains budget neutral by recalculating the policy's impact to make certain the conversion factor is properly adjusted.** This approach is consistent with other budget-neutral policies included in OPPS, such as wage index, outliers, rural SCH adjustment, and cancer hospital adjustment, for which adjustments are analyzed and made annually via the OPPS conversion factor.

In conclusion, payment cuts of the magnitude that HHS proposes directly contravene the intent of the 340B program and will only result in the loss of resources and services at the worst possible time for these hospitals and the patients and vulnerable communities they serve. While the AHA supports the goal of bringing down drug prices for Americans, reducing payments to 340B hospitals do nothing to address the skyrocketing costs of pharmaceuticals. Therefore, the AHA continues its call on HHS to

[20] https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf.
[21] https://www.aha.org/news/headline/2018-09-24-aha-comments-oppsasc-proposed-rule-cy-2019.

end this flawed policy and restore payments to 340B hospitals and to the patients and communities they serve.

PROPOSED CHANGES TO THE INPATIENT-ONLY LIST

The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting. This is due to the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Currently, the IPO list includes approximately 1,740 services.

CMS proposes to eliminate the IPO list over the three-year period, 2021 through 2024. For 2021, it would remove 266 musculoskeletal services from the list. In its discussion, CMS notes that it believes physicians should use clinical judgment, together with consideration of the beneficiary's specific needs, to select an inpatient or outpatient setting for care.

The AHA strongly urges CMS not to finalize its proposal to eliminate the IPO list over three years. The IPO list was put into place to protect beneficiaries. Many of its services are surgical procedures that are high risk – complicated and invasive procedures with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. 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 could make these procedures even more complicated and risky if furnished in outpatient settings.

The appropriate setting for procedures should be determined with a focus on patient safety and peer-reviewed evidence. However, CMS is proposing to remove certain procedures that do not have data to support the appropriateness of their performance in the outpatient setting. For instance, there are some services on the IPO list that may never be appropriate to furnish in an outpatient setting and certainly should not be removed from the list within the next three years. These include, for example:

- CPT code 33935 Transplantation heart/lung;
- CPT 32853 Lung transplant double;
- CPT code 19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation); and
- CPT code 3352 Coronary artery bypass, using venous graft(s) and arterial graft(s), six or more.

These services, as well as many others among the more than 1,700 services on the IPO list, could not be performed safely in hospital outpatient settings because of the

complex and high risk nature of the procedure and the fact that they require far more than 24 hours of postoperative recovery and monitoring time before the patient could be safely discharged.

We also are concerned that, even among the 266 musculoskeletal services proposed for removal in CY 2021, there are procedures without adequate data to support the appropriateness of their performance in the outpatient setting. According to the American Association of Orthopaedic Surgeons (AAOS), "Finalizing this policy as proposed will mean that complicated procedures from major trauma, such as pelvic, acetabulum, hip and fragility fractures and amputation that are mostly done with heavy inpatient monitoring, will be paid in the outpatient setting. AAOS experts believe that even with advances in medical practice, such procedures cannot be safely done in the outpatient setting currently." The AHA agrees. There are many musculoskeletal procedures among the 266 which are high risk and would require more than 24 hours of recovery or monitoring time. For example, these include the facial reconstruction CPT codes 21141 through 21436 and the arm and forearm replantation surgeries CPT codes 20802 and 20805. Eliminating these procedures from the IPO list would pose serious risks and have negative quality of care implications for vulnerable Medicare patients.

Given the depth and breadth of services that are the IPO list, as discussed above, it is premature to adopt a policy to eliminate the IPO list over three years. Instead, CMS should continue with its standard process for removing procedures. It could enhance determinations about individual procedures that could be safely removed from the IPO list by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes.

Further, this proposal is premature because CMS does not have the claims, cost and other data that would be needed to appropriately determine into which ambulatory payment classifications (APCs) the procedures should be incorporated. It also does not have adequate data for creating new APCs to capture IPO list procedures. With over 1,700 IPO services, grouping procedures into APCs and creating new APCs where necessary will be a huge undertaking. Three years is clearly not enough time to do so.

In addition, we are concerned about the financial and administrative burden of the elimination of the IPO list over such a short period of time at the same time that hospitals are grappling with the COVID-19 pandemic. That is, when a procedure is taken off the IPO list, it tends to be generally healthier Medicare beneficiaries, with shorter lengths of stay whose care migrates to the hospital outpatient department, leaving the sicker and more complex patients as inpatients. Eliminating the entire IPO list over three years will magnify this impact on hospital costs. Furthermore, in the experience of our members, when CMS removes procedures from the IPO list, commercial payers adopt this policy as well, but Medicare's "option" for the outpatient setting becomes the commercial payer's justification for making it the default location. **It**

would be unconscionable to finalize this policy when the financial impact of the COVID-19 PHE has already been devastating for hospitals – and there still remains an uncertain future as to the path of the pandemic.

MEDICAL REVIEW OF CERTAIN INPATIENT HOSPITAL ADMISSIONS UNDER MEDICARE PART A FOR CY 2021 AND SUBSEQUENT YEARS

CMS proposes to continue the two-year exemption from site-of-service claim denials under Medicare Part A, eligibility for beneficiary and family-centered care quality improvement organizations referrals to Recovery Audit Contractors (RACs) for non-compliance with the two-midnight rule, and RAC reviews for "patient status" for services removed from the IPO list under the OPPS in 2021 and subsequent years. However, given that many more services would be removed from the IPO list during the proposed transition, CMS is seeking comment on whether to retain or lengthen the two-year exemption.

If CMS eliminates the IPO list despite the concerns expressed by the AHA and others, we recommend that it abide by its ongoing deference to the physician's judgement on the appropriate site of care and exempt providers from site-of-service claims denials beyond the current two-year period. Two years is not enough time for adequate evidence and research to be conducted to demonstrate that procedures removed from the IPO list can be performed safely for Medicare beneficiaries in hospital outpatient settings. **As such, we recommend that CMS extend the medical review exemption period until such evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis.**

CHANGES IN THE LEVEL OF SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES

For CY 2020, CMS changed the minimum required level of supervision from direct supervision to general supervision for most hospital outpatient therapeutic services provided by hospitals and critical access hospitals (CAHs). The AHA strongly supported this change, as we have repeatedly urged CMS for such a solution to this critical issue for rural hospitals since it was put forth in 2010. However, some groups of services, including non-surgical extended duration therapeutic services (NSEDTS)[22] and pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation, were not subject to the change in the required supervision level; those services continue to have a minimum default level of supervision that is higher than general supervision.

[22] NSEDTS describe services, such as chemotherapy infusion services, that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS currently is direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising practitioner.

On Mar. 31, CMS issued an interim final rule with comment period (IFC) that gives Medicare providers needed flexibilities to respond effectively to the COVID-19 pandemic. In the IFC, the agency adopted a policy to reduce, during the PHE, the level of supervision for NSEDTS to general supervision for the entire service, including the initiation portion of the service, for which CMS had previously required direct supervision. The agency also specified that, for the duration of the PHE, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services includes the virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

While these policies were adopted on an interim final basis for the duration of the PHE, in the CY 2021 proposed rule, CMS indicates that it believes that they are appropriate outside of the PHE and should apply permanently. Therefore, the agency proposes to adopt these policies for CY 2021 and beyond**.**

The AHA strongly supports CMS's proposal to permanently establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after Jan. 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most other outpatient hospital therapeutic services and, as AHA has advocated for many years, will allow small and rural hospitals additional flexibility to provide these critical services in underserved locations.

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

- It would allow greater flexibility in providing these services and reduce provider burden, thus improving access to these services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner (NPP);
- A minimum requirement for general supervision does not preclude hospitals from providing direct supervision for any part of a NSEDTS when the physicians or NPP ordering or administering the medical procedure decides that it is appropriate to do so; and
- There are other requirements that apply to hospitals and physicians and NPPs which would complement the general supervision requirements for NSEDTS 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.

The AHA also supports, with one key reservation, CMS's proposal that for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac

rehabilitation services, the required direct supervision could include the virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We agree that the policy to allow direct supervision provided by the virtual presence of the physician would continue to improve access for patients and reduce burden for providers after the end of the PHE.

However, we are concerned about, and urge CMS not to finalize, its clarification that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. Requiring real-time presence throughout the procedure, rather than "immediate availability," is inconsistent with the statutory and regulatory definition of "direct supervision." It is, in fact, more akin to "personal supervision." As included in current regulatory definitions of "direct supervision" as well as the statutory language that defines the required level of supervision for cardiac rehabilitation, pulmonary rehabilitation and intensive cardiac rehabilitation programs, "direct supervision" does not require the presence of the physician for the duration of the service; rather it requires only that the physician be "immediately available" to furnish assistance, as necessary, through the performance of the procedure.

That is, 42 CFR 410.28(e)(1), as updated by the IFR, defines direct supervision as:

> "the physician must be *immediately available* to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in §400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider."

Further, Section 1861(eee)(2)(B) of the Social Security Act establishes that, for cardiac, intensive cardiac and pulmonary rehabilitation programs, "a physician is *immediately available* and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed." This statutory requirement is very similar to the requirement for direct supervision.

Neither definition of the direct supervision for these services mandates more than the *immediate availability* of the physician throughout the service. However, CMS's clarification is closer to the definition of personal supervision (42 CFR 410.32(b)(3)(iii)), which means that "the physician must be in attendance in the room during the performance of the procedure" – than direct supervision. A personal level of supervision is unnecessary for these services (which are only furnished to stable outpatients) and is

inconsistent with the statutory requirement of direct supervision for cardiac, pulmonary and intensive cardiac rehabilitation services.

The AHA strongly urges CMS not to finalize this clarification but rather allow the supervising physician to be *immediately available* to furnish assistance and direction throughout the service using audio/video real-time communications technology.

PROPOSED NEW CATEGORY OF LAB TESTS EXCLUDED FROM OPPS PACKAGING

Under current CMS policy, most clinical diagnostic laboratory tests are packaged under the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. However, certain laboratory tests, including molecular pathology tests, remain separately payable under the Clinical Laboratory Fee Schedule (CLFS).

In the CY 2021 proposed rule, CMS proposes to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests from the OPPS packaging policy and pay for them separately under the CLFS. The AHA agrees with CMS that cancer-related protein-based MAAAs – similar to molecular pathology tests – are relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

Therefore, the AHA supports CMS's proposal that protein-based MAAA tests to diagnose cancer should no longer be packaged into OPPS payment.

SPECIMEN COLLECTION FOR COVID-19 TESTS

As result of the COVID-19 PHE, CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [covid-19]), any specimen source). HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures for the duration of the COVID19 PHE, with a payment rate of $22.98 for 2020. HCPCS code C9803 is conditionally packaged meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable.

We recommend that CMS retain HCPCS code C9803 and its current APC assignment and status indicator beyond the COVID-19 PHE.

PAYMENT FOR BLOOD NOT OTHERWISE CLASSIFIED (NOC) CODE

Starting Jan. 1, 2020, CMS established a new HCPCS code, P9099 (Blood component or product not otherwise classified), which allows providers to report unclassified blood products before blood product-specific HCPCS codes are available. For CY 2020, HCPCS code P9099 has a status indicator (SI) of "E2" (Not payable by Medicare when submitted on an outpatient claim) because the code potentially could be reported for multiple products with different costs during the same period of time.

For CY 2021, CMS proposes to change the SI for HCPCS code P9099 from "E2" to "N" (payment is packaged into other services in the OPPS) and package the cost of the unclassified blood products into their affiliated primary medical procedure. In addition, CMS also seeks comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. With the alternative option, the SI for HCPCS code P9099 would change from "E2" to "R" (blood and blood products, paid under OPPS).

We agree with the Advisory Panel on Hospital Outpatient Payment recommendation that CMS change the SI to "R" for HCPCS code P9099, with a payment rate based on the weighted average of all blood/blood products APCs. Providers should receive separate reimbursement for new blood/blood products, as they incur a cost for these products, and costs for new and existing products are not included in any current APCs since CMS does not package blood or blood products.

HOSPITALS WITHOUT WALLS

During the PHE, CMS created a category of flexibilities called "Hospitals without Walls," under which hospitals are able to establish and operate in any location as a PBD of the hospital, including a patient's home, if they meet certain requirements. These flexibilities ensured that patients remained connected to essential services from the safety of their homes and hospitals retained inpatient capacity for those who need it most. Indeed, the Hospitals without Walls waivers had a profoundly positive effect on hospitals' abilities to manage the pandemic; they enabled patient access to services delivered by hospital clinical staff – such as diabetes self-management training, medical nutrition therapy, and behavioral health counseling, and many others – and ensured hospital administrative staff could continue to support providers delivering virtual services and patients receiving those services. This is especially important given the numerous added steps hospitals must undertake to execute a virtual visit. These steps include:

equipping providers with necessary hardware; acquiring professional licenses for each physician on the virtual platform the hospital chooses; conducting separate communication with patients to test software, complete pre-registration, obtain and record patient consent, and conducting intake before a visit and follow-up after it, all of which would normally be done in person.

Our members report that patients have been extremely satisfied with their experiences receiving virtual care from all of the places they can currently access in-person care, including hospital outpatient departments. Patients have found that the convenience, quality and ease of receiving care in this manner helps accommodate their individual needs and lifestyles, creating a safer, more patient-centered care experience. **As such, we urge CMS to continue the Hospital without Walls flexibilities to the greatest extent possible. We recognize that this may require legislation and urge the agency to work with us and Congress to ensure hospitals and health systems can continue providing high-quality virtual care for their patients and communities.** We refer you to our comments the CY 2021 Physician Fee Schedule proposed rule for additional recommendations on virtual care.

PROPOSED CHANGES TO THE LIST OF ASC-COVERED SURGICAL PROCEDURES

Proposed Additions to the List of ASC-covered Surgical Procedures. CMS conducted its annual review of procedures paid under the OPPS, but not included on the list of covered ASC procedures. As a result, for 2021 CMS proposes to add 11 procedures to the ASC-covered procedures list (CPL). Among these is CPT code 27130, Total Hip Arthroplasty (THA).

We urge CMS not to add THA to the ASC-CPL, as it would be clinically inappropriate. Specifically, doing so would pose serious risks and 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 in an ASC for some 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 hospital-based settings. Managing post-operative pain for THAs performed in ASCs 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 an ASC. This setting would 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.

Moreover, 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 THA; beneficiaries will most likely face higher copayments in ASCs than in HOPDs. This is because, in the HOPD, the beneficiary copayment amount is capped at the inpatient deductible amount, which is $1,408 in 2020[23]. There is no copayment cap in ASCs. In the OPPS, CPT 27130 (THA) is part of C-APC 5115, Level 5 Musculoskeletal Procedures, proposed to be paid at $12,559 in CY 2021. Therefore, the 20% copayment for C-APC 5115 ($2,512) would exceed the Medicare Part A inpatient deductible and 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 THA would be subject to an additional 20% copayment. For CY 2021, CMS proposes a payment rate for CPT 27130 (THA) of $8,924, which would result in a copayment of $1,785. This is already $377 more than the beneficiary copayment in the HOPD and does not even include all the other separately payable services likely furnished along with a THA in the ASC setting. Therefore, the out-of-pocket costs for Medicare beneficiaries could be significantly higher in an ASC than in an HOPD.

In addition to the inherent risks associated with THA for older patients and the higher co-payment that beneficiaries will face when these procedures are furnished in ASCs, part of our concern is that independent ASCs are often physician-owned and are not subject to the Stark self-referral regulations. Therefore, there may be other incentives in place for physicians in making a determination of the appropriate site-of-service.

Alternative Proposals for Adding New Procedures for the ASC-CPL. CMS proposes two alternatives that would each significantly modify the agency's process for adding surgical procedures to the ASC-CPL. Under both alternatives, CMS would retain the general standards specified in regulations for adding ASC-covered surgical procedures, including that the procedures:

- Are separately paid under OPPS;
- Are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC; and
- A beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure.

[23] The 2021 inpatient deductible amount has not yet been announced but will likely increase in 2021.

However CMS would eliminate five of the general exclusion criteria currently in the regulations. Specifically, it would eliminate criteria that ASC-covered surgical procedures do not include surgical procedures that:

- Generally result in extensive blood loss;
- Require major or prolonged invasion of body cavities;
- Directly involve major blood vessels;
- Are generally emergent or life threatening in nature; and
- Commonly require systemic thrombolytic therapy.

Further, CMS would revise another general exclusion criterion which currently excludes procedures on the IPO list from being added to the ASC-CPL. That is, in light of the proposed elimination of the IPO list, CMS proposes to modify this criterion to exclude procedures that that were on the IPO list as of Dec. 31, 2020 from being added to the ASC-CPL.

Under Alternative 1, in addition to making the changes to the regulatory exclusion criteria described above, CMS would solicit nominations from external stakeholders for procedures that could be added to the ASC-CPL. CMS would make final determinations regarding which nominated procedures would be added to the ASC-CPL through annual rulemaking. The nomination process would begin in 2022, which would result in surgical procedures potentially being added to the ASC-CPL beginning in 2023.

Alternative 2 would have a more immediate and potentially broader impact on the ASC-CPL. As with the first, in this second alternative CMS proposes to make all the same changes to the regulatory exclusion criteria as described above. While CMS would use a process similar to its current annual review process, the reduced number of regulatory exclusion criteria would result in procedures being added to the ASC-CPL more quickly. In fact, the agency identifies 270 possible surgery or surgery-like codes that it believes would meet the proposed revised criteria for 2021. CMS also seeks comments on whether it should revise the ASC Conditions for Coverage (CfCs) or quality metrics in response to an expanded range of services that may be covered under Medicare in the ASC setting.

The AHA strongly opposes both proposals to modify the agency's process and criteria for adding surgical procedures to the ASC-CPL. The current regulatory general inclusion and exclusion criteria serve two critical purposes. First, they are important patient safety guardrails intended to exclude from coverage those procedures that would pose a high-risk of complications that ASCs are not equipped to handle. Second, they allow appropriate surgical procedures to be added to the ASC-CPL. **It is not appropriate for CMS to eliminate such meaningful patient safety guardrails. For example, the agency should not eliminate a criterion that prevents a provider that does not have emergency capabilities from conducting surgeries that are**

emergency or life-threatening in nature. Therefore, the AHA strongly recommends that CMS preserve these five general exclusion criteria. As has been demonstrated in recent years, the existing ASC regulatory criteria have supported the ability of ASCs to safely furnish an expanding range of surgical procedures as innovations in surgical care occur. However, because ASCs are not subject to the same level of regulatory oversight as hospitals and are not equipped to manage emergencies that require lifesaving hospital inpatient capabilities, keeping these general exclusion criteria in place will prevent surgical procedures that pose significant threats to beneficiary safety and quality of care from being performed in in ASCs. **Furthermore, although the AHA strongly opposes CMS's proposal to eliminate the IPO list, as stated above, if the agency were to nevertheless finalize this policy, we also urge CMS to finalize its proposed revision that would prevent procedures that were on the IPO list as of Dec. 31, 2020 from being added to the ASC-CPL.** Procedures that would be removed from the IPO during the proposed three-year phase-out have not been evaluated for clinical appropriateness in a hospital outpatient department setting and are clearly inappropriate for coverage in the ASC setting.

In addition, the AHA strongly opposes CMS's proposal, under Alternative 2, to add 270 surgery or surgery-like codes to the ASC-CPL that it believes would meet the proposed revised criteria for 2021. CMS proposed these additions without taking into consideration the five regulatory exclusion criteria it has proposed for removal, and which we believe are essential to protect beneficiaries. The agency also does not provide any rationale that these procedures meet even the general regulatory standards for adding ASC-covered surgical procedures that CMS proposes to retain. **For example, CMS did not provide any evidence that these procedures are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, or that a beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure. In fact, many of the procedures CMS proposes would *not* meet the agency's own criteria and we are extremely confused as to why it is proceeding down this path.** For instance, consider CPT code 21172, Reconstruction of the superior-lateral orbital rim and lower forehead; CPT code 37619, Ligation of inferior vena cava, and CPT code 63016, Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, more than 2 vertebral segments. The American Medical Association's Relative Value Update Committee assigns a total service time for each of these services of 11 hours or more. **As such, not only would these procedures pose a significant safety risk to the beneficiary if done in an ASC, but also, given their duration, they would likely require active medical monitoring and care at midnight following the procedure.** These are just a few of the many procedures included among the 270 CMS proposes for ASCs that would be safer to perform in a hospital-based setting.

Furthermore, although the AHA strongly opposes the proposed changes to the ASC-CPL process and criteria, if the agency were to nevertheless finalize either proposed Alternative 1 or 2, we urge it to work with clinical experts and other stakeholders to make appropriate changes to the ASC CfC in response to the expanded range of higher risk services that would be covered in the ASC setting. There are complications associated with any major surgery, such as anesthesia-related risks, allergic and other medication reactions, and those related to comorbid medical conditions. ASCs are not equipped to handle such life-threatening events, and we anticipate that if CMS finalizes its proposal, many patients would be sent emergently from ASCs to the nearby hospital ED when such complications arise. Therefore, we recommend that CMS start by restoring some of the beneficiary protections that the agency recently removed.

In last year's Medicare and Medicaid burden reduction final rule[24], CMS weakened the CfC requirements that mandate that there is a plan in place in the event such emergencies arise. That is, it eliminated the requirement that ASCs have a written transfer agreement with a nearby hospital or ensure that its physicians have admitting privileges at a hospital. Instead, the agency now only requires ASCs to periodically provide the local hospital with written notice of its operation and patient population served. As a result, if a patient has a medical emergency that cannot be addressed within the capabilities of the ASC, it need only call an ambulance and send the crashing patient to the nearest hospital ED, without any further responsibility for the beneficiary's condition**. In light of the proposal to add so many complex, invasive surgical procedures to the ASC-CPL, CMS should restore the CfC requirements regarding written hospital transfer agreements or physician admitting privileges at a hospital.**

Furthermore, with a broad expansion in the number and kinds of procedures that are proposed for addition to the ASC-CPL, including procedures that may have never been furnished in this setting, even greater oversight is necessary to protect Medicare beneficiaries. CMS should consider coordinating with clinical experts on enhancements to the anesthesia, emergency equipment and discharge planning standards. The agency suggests several possible changes that AHA agrees may be worth pursuing, including:

- That risk evaluations should be more prescriptive and attest that an individual patient can safely undergo the procedure in an ASC;
- A requirement that an adequate number of nurses be on duty in the ASC;
- A requirement that staff certified to provide Advance Cardiac Life Support be present in the ASC in the event of life threatening emergencies; and
- Specific CfC requirements that ASCs would need to meet for particular patient conditions or more complex and invasive surgical procedures.

[24] https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf.

Finally, in addition to the inherent risks associated with more complex services being performed in the ASC setting, beneficiaries may also unexpectedly face higher out-of-pocket costs for surgeries performed in an ASC than they would if the services were furnished in a hospital outpatient department. This is especially a concern because physician-owners of ASCs are not subject to the Stark self-referral regulations and so may have a personal financial interest in performing surgery at an ASC instead of a hospital. **To ensure that beneficiaries are aware of this potential increased financial liability, the AHA recommends that the ASC CfC patient rights section be revised to include a condition requiring that ASCs inform patients in writing, prior to their procedure, of their copayment obligation and that, by virtue of services being performed in an ASC rather than a hospital outpatient department, they may be incurring higher out-of-pocket cost, and the difference in amount.**

OVERALL HOSPITAL STAR RATINGS PROPOSALS

CMS proposes to implement significant modifications to the overall hospital star ratings methodology starting in CY 2021, and to codify a number of existing procedures and policies in regulation. Among other changes, CMS would simplify the calculation of measure group scores by eliminating the use of latent variable modeling (LVM). CMS also proposes to calculate hospitals' readmission measure group scores by placing hospitals into one of five peer groups based on their proportion of dual-eligible patients, an approach aligned with that of the Hospital Readmissions Reduction Program (HRRP). Lastly, before determining the final overall star rating, CMS would place each hospital into one of three peer groups based on the number of measure groups it reports. We comment on these and several other star ratings proposals below.

General Considerations. As longstanding supporters of transparency, America's hospitals and health systems believe that patients, families and communities should have valid, clear and meaningful quality information to help them make important health care decisions. That is why the AHA has long urged CMS to address the substantial flaws in the current star ratings methodology. As noted in our response to the agency's star ratings RFI in 2019, we believe the "must have" elements to any star ratings approach include:

- *Usefulness to consumers.* The ratings should provide information that is relevant to the wide range of reasons patients seek hospital care, and give consumers the ability to drill down on the particular aspects of care most relevant to them.

- *Accuracy.* The ratings should be based on rigorous quality measures, and employ appropriate, correctly-executed statistical approaches to combining performance across measures. Users and hospitals should expect that differences in star ratings across hospitals are substantiated by clinically and statistically meaningful differences in underlying performance.

- *Stability.* Any fluctuations in star ratings across reporting periods should be driven by significant changes in underlying measure performance rather than by any inherent instability in the ratings methodology.

- *A "line of sight" from star ratings to performance on underlying measures.* Because star ratings are publicly reported, hospitals should be able to see how any positive or negative changes in underlying measure performance are reflected in their star ratings in a transparent and predictable fashion.

- *Balanced assessment.* Star ratings performance should be based on performance across the breadth of available measures, and not hinge disproportionately on only one or two measures.

- *Accounts for potential biases.* The ratings must account adequately for differences in the clinical and social risk factors across the patients and communities that hospitals serve. Hospitals that serve sicker and poorer patients should be on a level playing field with all other hospitals.

The AHA commends CMS for proposing changes that attempt to address all of these elements in a serious way. We urge CMS to adopt its proposals to discontinue the use of the LVM approach to measure group scores, and to stratify hospital readmissions measure group scores by the proportion of dual-eligible patients. However, while we agree with the intent behind CMS's proposal to peer group hospitals, we encourage the agency to explore additional alternative peer grouping approaches before finalizing it.

Lastly, our support for many of CMS's proposed changes notwithstanding, we continue to question the basic concept of a single, overall rating of hospital performance. That is because the measures included in the ratings were never intended to create a single, representative score of hospital quality. Furthermore, the ratings often do not reflect the aspects of care most relevant to a particular patient's needs. For example, a family may be interested in selecting the best hospital for cancer care, but there is only one such measures included in the current star ratings. In addition, there is vast variation in the type, scope and mix of services that hospitals provide. **For these reasons, we continue to encourage CMS to consider developing an alternative approach in which star ratings are done only by topic area such as patient safety, patient experience of care and cardiac care.** This approach may increase the relevancy of ratings information to consumers, and lessen the possibility of consumers receiving misleading information about quality.

Reorganization of Measure Groups. **The AHA supports CMS's proposed reorganization of star ratings measure groups.** Specifically, CMS would consolidate the current effectiveness of care, timeliness of care and efficient use of medical imaging

groups into a single group called “Timely and Effective Care,” and give it a weight of 12%. We agree that because so many of the measures in the previously separate measure groups have been removed from CMS programs, it would be both conceptually and statistically inappropriate to retain separate measure groups.

Measure Group Scores – Elimination of LVM in Favor of Simple Average. **The AHA supports CMS’s proposal to discontinue the use of the LVM approach in calculating measure group scores and instead use a simple average of measures in the group.** The LVM combines actual measure performance with statistical assumptions about unobserved (or latent) dimension of quality that are based on available measure data. While CMS initially adopted LVM in an attempt to provide statistical rigor, our members have raised two major concerns about its use in star ratings. First, LVM is an inherently complex statistical modeling technique, impinging on hospitals’ “line of sight” between how their underlying measure performance translated into a star rating. This made it hard for hospital leaders to explain to staff, governance boards and the public why they may have received a particular rating, and what they could do to improve it. Given how public the ratings are, the lack of transparency introduced by LVM is unacceptable.

Second, the LVM introduced unwarranted volatility into star ratings, stemming from the LVM’s approach to calculating measure “loading factors.” Because each measure’s loading factor can change when CMS calculates it each year, the degree to which any one measure drives performance in a measure group also can change. As a result, the ratings were of virtually no use to internal quality improvement efforts, and hospitals had extremely limited ability to prioritize improvement efforts on any particular measures within star ratings. As noted in the previous section, we believe changes in star rating performance must be based on real changes in underlying measure performance, rather than the inherent design of the methodology.

We agree with CMS that taking an average of the measures in the group would result in a less statistically rigorous approach to star ratings. However, the benefits of transparency far outweighs that drawback. Hospitals would now know exactly what weight particular measures would have in star ratings, and follow a simple calculation of how measure scores would be summed into a group score. Using a simple average also makes it possible to use star ratings as one mechanism to track progress on internal improvement priorities. This approach would also make it more transparent to the public what weight is applied to each of the measures. For example, most would likely be unaware that because of the LVM, three measures – hip/knee complications, hospital-wide readmissions and the claims-based patient safety indicator measure – were previously driving nearly all of the determination of what star rating a hospital received. Other measures of greater importance to patient safety, such as health care associated infections, had very little weight.

Measure Group Scores – Stratifying the Readmissions Measure Group. **The AHA supports CMS’s proposal to stratify the calculation of readmission measure**

group scores by hospitals' proportions of dual-eligible patients using an approach consistent with that of the HRRP. This proposal responds directly to our recommendation to ensure a level playing field among hospitals in calculating star ratings. In addition, the alignment between the HRRP and star ratings approach to dual-eligible stratification is especially welcome since most hospitals already are familiar with the HRRP's approach, and would have to track only one approach to dual-eligible stratification. However, we note that the HRRP's stratification approach will be new for any CAHs receiving a readmissions group score because CAHs do not participate in the HRRP. For that reason, we encourage CMS to target technical support resources to CAHs to help educate them on the approach. This includes webinars, fact sheets and potentially a CAH-targeted "dry run" so that they know which peer group to expect when they receive preview reports.

A body of peer-reviewed literature shows that performance on readmission measures is driven not only by the quality of hospital care, but also by social risk factors beyond hospitals' control, such as income and insurance status. To date, hospitals caring for sicker patients and poorer patients tend to fare worse on star ratings. Specifically, teaching hospitals, hospitals that report on larger numbers of star ratings measures, and hospitals receiving the highest disproportionate share hospital (DSH) payments (a proxy for the extent to hospitals serve the poor) all have ratings that are, on average, lower than other hospitals. For that reason, the AHA has long urged CMS to account for the impact of social risk factors in calculating star ratings. While a range of outcome measures may require adjustment, we have urged CMS to prioritize a social risk factor adjustment for the readmissions measure group.

While we support CMS's proposal, the AHA continues to urge CMS to view stratification as an interim strategy while it assesses ways to improve its approach to accounting for social risk factors in readmission measures. As we have noted with CMS's implementation of dual-eligible peer grouping in the HRRP, there are some inherent shortcomings with stratification, including somewhat subjective choices about where to set the cut points of a particular group. For example, those hospitals at the upper end of one group and those at the lower end of the next group would have similar proportions of dual-eligible patients, but would be placed into different groups for performance comparison purposes. Furthermore, direct risk adjustment would help improve the precision of performance comparisons by ensuring that measure scores reflect the issues most relevant to each measured outcome. For example, the stratification approach relies on the assumption that dual-eligible status is equally large determinant of performance for all of the readmission measures, when in fact, the impact of dual-eligible status may be slightly different for each measure.

In exploring alternative approaches to accounting for social risk factors, we also urge CMS to reject the findings of the recent report from the Assistant Secretary for Planning and Evaluation (ASPE) that CMS cites in the rule. ASPE's report contends, among other things, that adjusting for social risk factors is inappropriate, and recommends the removal of the HRRP's stratification approach. Indeed, we are perplexed by these

findings given that they run counter to the ample peer-reviewed literature showing the extent to which social risk factors drives performance. Indeed, ASPE itself issued a report in 2016 showing that social risk factors had an impact on nearly every CMS quality measurement program. Furthermore, we note that CMS does not have the statutory authority to remove dual-eligible stratification from the HRRP unless it adopts an alternative approach to accounting for social risk factors in calculating readmissions performance.

Star Rating Reporting Thresholds, **The AHA supports CMS's proposal to change the star rating reporting thresholds.** CMS proposes that hospitals would receive a star rating only if they report at least three measures in at least three measure groups, one of which must be mortality or safety. We agree with the agency that these two topics are of foundational importance to both patients and hospitals.

Assignment of Hospitals to Peer Groups. **The AHA agrees with the principle behind CMS's proposal to peer group hospitals by the number of reported measure groups. However, we encourage CMS to continue exploring additional alternative peer grouping approaches before finalizing this approach.** The current star ratings methodology compares all hospitals that meet the inclusion criteria directly to one another. Yet, as CMS notes, hospitals have significant variations in size, patient volume, case mix and services provided. As a result, many stakeholders have suggested the current methodology may result in potentially misleading comparisons among hospitals. In response, CMS proposes to place hospitals into one of three peer groups based on the number measure groups they report.

Peer grouping approaches attempt to create groupings of hospitals that are similar to one another on one or more specific characteristics, and compares performance within those groupings. We agree with the basic concept behind peer grouping – that is, it may be fairer to compare hospitals that are similar to one another than it is to compare hospitals with very different characteristics. However, the most challenging aspect of designing any peer grouping approach is selecting the variable(s) around which the groupings are organized. Generally speaking, peer grouping variables should be collected in a consistent manner, be consistently associated with star ratings performance, but also be characteristics over which hospitals have little influence. Hospitals have suggested CMS consider a variety of potential peer grouping variables, including bed size, case mix index, number of reported measures, teaching status, CAH designation and proportion of dual-eligible patients, to name just a few.

In this case, CMS proposes to use the number of reported measure groups because it has a clear, consistent definition, and the agency believes it is a reasonable proxy for a number of other characteristics, including patient mix and bed size. We certainly agree that the number of reported measure groups is easy to calculate. Yet, it less clear whether this characteristic is as strong a proxy for other underlying factors as CMS believes, and unfortunately, the analysis CMS includes in the rule does not allow us to assess this question directly.

Furthermore, we note there are significant differences in the sizes of the three peer groups, making us question the extent to which comparability is improved. CMS estimates that 10% of hospitals report three measure groups, 17% report four measure groups, and 73% report five measure groups. We believe the sheer size of the largest peer group means that the hospitals within it would continue to have significant variation in bed size and patient mix. For example, it would be possible for a smaller hospital to report all five measure groups, but report only the minimum number of measures (3) within each group. That hospital could be compared directly to a large hospital with enough volume and breadth of services to be scored on all measures included in star ratings.

Lastly, we note that the measures used in star ratings will continue to evolve in the coming years. CMS's Meaningful Measures initiative has removed a significant number of measures from hospital programs. While we strongly supported CMS's decision to streamline measures, it has implications for how many measures particular hospitals will be able to report. This may make the proposed approach to peer grouping inappropriate. Furthermore, the COVID-19 PHE prompted CMS to suspend quality reporting for the first two quarters of 2020, and may result in hospitals using the agency's extraordinary circumstance exceptions (ECE) policies to opt out of reporting for the rest of 2020. This also could affect a peer grouping approach based on the number of reported measure groups and potentially distort the sizes of the peer groups in unanticipated ways.

For these reasons, we encourage CMS to continue exploring a number of alternative approaches to peer grouping variables. For instance, the agency could examine whether it can create a composite of several characteristics – such as bed size, case mix, number of reported measures, teaching status, and the like – to use in organizing peer groups. Or, it could create peer groups based on the number of reported measures, instead of the number of measure groups. In exploring such changes, we urge CMS to make any analyses public, and to consult experts in the field using its existing Technical Expert Panel, the National Quality Forum, listening sessions and other mechanisms.

Critical Access Hospitals. **The AHA supports the continued inclusion in star ratings of those CAHs that choose to report quality data and opt into having their star ratings reported publicly.** While CAHs are not required to participate in the CMS hospital quality measurement programs, many opt to submit quality measure data, and appreciate the opportunity to see how their star ratings performance might compare to that of other CAHs and other hospitals.

The AHA also supports the structure of CMS's proposed "opt out policy." We also encourage CMS to provide ample technical assistance to CAHs – including webinars, ongoing communications and help desk assistance – to ensure they know how to avail themselves of the final opt-out policy.

Veterans Health Administration (VHA) Hospitals. **While we are open to the concept of including VHA hospitals in star ratings, AHA urges CMS not to finalize a policy to include them until it provides additional details on how it would operationalize such a policy.** Beginning in CY 2023, CMS would include VHA hospitals in star ratings. Citing the same authority under section 1704 of the Public Health Service Act as it does for CAHs, CMS notes its interagency agreement with the VHA would allow it to publish their hospitals' quality data.

Yet, it is not clear whether VHA hospitals are – or will – report on all of the same measures as the other hospitals included in star ratings. Furthermore, as CMS notes, even if VHA hospitals do report the measures, they are not included in Medicare quality reporting programs. The statistical impact of VHA hospitals on many measures – especially those based only on Medicare claims data – is simply unknown at this point. Unless and until the agency can provide additional detail, we do not think it would be appropriate to add VHA hospitals to star ratings.

Frequency and Timeframe of Star Rating Updates. **The AHA supports CMS's proposal to continue updating star ratings once per year.** We agree this approach should help make the ratings more stable, and allow hospitals additional time to know how their performance on the underlying measures might translate into a star rating.

Star Ratings Suppression for Subsection (d) hospitals. **In general, the AHA supports CMS's proposed star ratings suppression policy for subsection (d) hospitals.** Such hospitals must participate in CMS hospital quality programs. CMS would suppress the publication of star ratings only under circumstances that affect numerous hospitals as determined by CMS, or when CMS is at fault.

However, we urge CMS to consider adding a criterion in which it suppresses ratings in the event a hospital or one of its agents (such as an authorized vendor) submits inaccurate data. We agree with CMS that hospitals have mechanisms within exiting reporting programs to correct underlying data before they are submitted. However, it is still possible that even after a hospital reviews the data their vendor intends to submit, there can be data transmission problems that hospitals may not pick up on until the star ratings preview period. We believe such instances would be extremely limited, but believe the agency should provide a mechanism to suppress the ratings when there is insufficient time for the data to be corrected before publication.

PROPOSED REVISION TO THE LABORATORY DATE OF SERVICE POLICY UNDER THE CLINICAL LABORATORY FEE SCHEDULE

Many hospitals do not perform in-house more technologically advanced laboratory tests, such as molecular pathology and advanced diagnostic laboratory tests (ADLTs)[25], 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. However, hospitals still often must bill Medicare for these laboratory tests that they do not perform due to CMS's laboratory date-of-service (DOS) policy and the "under arrangements" regulations. In these circumstances, the laboratory must seek payment for these tests from the hospital.

In the CY 2018 OPPS/ASC final regulation, in response to concerns that the DOS policy was administratively burdensome for hospitals and for the 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 enables independent laboratories performing certain ADLTs and molecular pathology tests excluded from the OPPS laboratory test packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital. The exception established 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 hospital outpatient department;
- 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.

Proposed Revision to Laboratory DOS Policy. In the proposed rule, CMS notes that the pattern of clinical use of cancer-related, protein-based MAAAs, similar to molecular pathology tests and ADLTs, make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions.

[25] ADLTs are tests that are performed by a single laboratory only and meet other criteria specified in statute.

Therefore, for the same reasons that CMS proposes to no longer package cancer-related protein-based MAAAs under OPPS, CMS also proposes to apply the DOS exception to these MAAA tests. This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not packaged and the DOS policy described above is met.

The AHA supports this proposed policy. It would create consistency between the laboratory DOS rules and the proposed change for the OPPS laboratory test packaging policy for MAAAs. Further, this change would improve access to critical diagnostic testing services for Medicare beneficiaries while reducing hospital administrative burden.

PHYSICIAN-OWNED HOSPITALS (POH)

For decades, the Stark Law has protected federal health care programs from the inherent conflict of interest created when physicians self-refer their patients to facilities and services in which they have a financial stake. In 2010, based on a decade of research on the adverse impacts of POHs, Congress strengthened that protection by imposing a prospective ban on self-referral to new physician-owned hospitals.

In this rule, CMS proposes to remove certain restrictions on the expansion of POHs that qualify as high Medicaid facilities. Specifically, CMS's proposals would (1) allow high Medicaid facilities to request an exception to the prohibition on expansion of POHs more frequently than once every two years; (2) remove the restriction that expansion of POHs may not result in the number of operating rooms, procedure rooms and beds for which the hospital is licensed exceeding 200% of the hospital's baseline number of operating rooms, procedure rooms and beds; and (3) remove the limitation that expansion may occur only in facilities on the POH's main campus.

The AHA strongly opposes the proposals in this rule and any other attempts to loosen the current restrictions on POHs. Recent data reinforces the need for a ban on new and expanded POHs. Specifically, an analysis conducted by the health care economics consulting firm Dobson | DaVanzo provides a clear picture that the characteristics of these hospitals virtually mirror the those that, in the early-to-mid 2000s, drove Congress to prospectively ban self-referrals to new facilities. For example, Dobson | DaVanzo found that POHs:

- Cherry-pick patients by avoiding Medicaid and uninsured patients;
- Treat fewer medically complex patients;
- Have margins nearly three times those of non-physician owned hospitals;
- Provide few emergency services – an important community benefit; and

- Are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals.

Another, more recent analysis performed by DeBrunner & Associates conducted in August underscores the fact that non-POH hospitals treat the sickest, most vulnerable patients. Specifically, we found that on average, patients discharged from non-POHs are 36% more likely to have one or more chronic conditions. At the same time, non-POH hospitals provide 25% more uncompensated care as a share of total expenses. Both of these trends contribute to the fact that POH hospitals have, on average, an operating margin that is *57 times higher* than non-POH hospitals.

In fact, the Congressional Budget Office, MedPAC and independent researchers have all concluded that physician self-referral to facilities in which they have an ownership stake leads to greater per-capita utilization of services and higher costs for the Medicare program. Further, POHs tend to cherry-pick the most profitable patients, jeopardizing communities' access to full-service care. This trend creates a destabilizing environment that leaves sicker and less affluent patients to community hospitals, threatening the health care safety net.

The proposals in this rule run counter to the sum total of the research in that they would make it easier for certain POHs to expand, putting high-quality, reliable care at risk. However, we are concerned that CMS understates this potential for POHs to expand. The agency states in the rule that only one POH per year would request an expansion under these proposals. In contrast, our analysis demonstrates that approximately 25 facilities could qualify over the next three years. We urge CMS to, at the very least, release the data upon which it based its conclusion.

In addition, some of the POHs that qualify as "high Medicaid facilities," and would thus be able to expand under this proposal, have extremely low Medicaid discharge percentages. They clearly do not embody the intent of the exception. Specifically, while they may have the highest Medicaid discharge percentages in their counties, those percentages are significantly lower than that of hospitals in surrounding counties. For example, one POH has a Medicaid discharge of 1.9%. That is higher than the only other hospital in the county, a rehabilitation hospital, but it is much lower than hospitals in surrounding counties, which have Medicaid discharge percentages as high as 96.3%. There are several other examples of this discrepancy, including:

- A POH with a 16% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 28.33%.
- A POH with a 19.1% Medicaid discharge percentage neighbors two counties with hospitals that have Medicaid discharge percentages as high as 66.1%.
- A POH with an 18.8% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 44.6%.
- A POH with an 18.8% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 53%.

CMS's proposals also create perverse incentives to game the limited exception to the prohibition on expansion of POHs, threatening to bust it open. Specifically, POHs could work to temporarily meet the high Medicaid facility threshold, allowing them to undertake a significant expansion. Because there are no requirements in the proposal to continue meeting the high Medicaid facility criteria following any such expansion, these POHs could then return to rejecting Medicaid and other patients. There also appears to be no restrictions on how frequently high Medicaid facilities can expand. These proposals pose grave risk to the stability and integrity of patient care and should not be finalized.

PROPOSED PRIOR AUTHORIZATION REQUIREMENTS FOR ADDITIONAL OUTPATIENT SERVICES

Continuing to cite its authority under section 1833(t)(2)(F)[26] of the Social Security Act and the regulations at 42 CFR § 419.83,[27] CMS proposes expand the prior authorization program it established in 2020 to two new service categories: cervical fusion with disc removal and implanted spinal neurostimulators. The prior authorization process for these two additional service categories would be effective for dates of services on or after July 1, 2021. 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 continues to oppose the OPPS prior authorization program and urges the agency to withdraw it. As stated in our CY 2020 comment letter, the prior authorization program is contrary to law because CMS must implement any methods developed under paragraph (t)(2)(F) through other provisions of the OPPS statute. In addition, the prior authorization program is arbitrary and capricious because the agency has not established that the increase in volume for these services is "unnecessary." Please refer to our Sept. 27, 2019 comment letter for additional information about these concerns.

CMS has not demonstrated that the increase on the volume of these services are "unnecessary." In the proposed rule, CMS describes claims data for a 12-year period, from 2007 through 2018, showing increases in the volume for implanted spinal neurostimulators and claims data for a seven-year period from 2012 through 2018 showing an increase in the volume of service utilization for cervical fusion with disc removal. 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) the agency is unaware of other factors that might contribute to

[26] "(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."
[27] 42 CFR § 419.83 - List of hospital outpatient department services requiring prior authorization.

clinically valid increases in volume, such as "legitimate clinical or coding reasons for the changes."

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 "did not find any explanations that would cause us to believe the increases were necessary." 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.[28] An agency may not adopt an "ostrich-like approach" to decision-making,[29] 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.[30]

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, or because CMS's own policies are incentivizing increased outpatient utilization of these services or otherwise encouraging the shifting of these services from inpatient to outpatient settings.

As discussed below, there are medically necessary indications for both of the categories of procedures that would be subject to prior authorization, and shifts in national policy and CMS's Medicare policies that could explain the increases in volume. It is disappointing that the agency chose not to undertake these types of relatively straightforward analyses, and instead chose to set forth unfounded proposals.

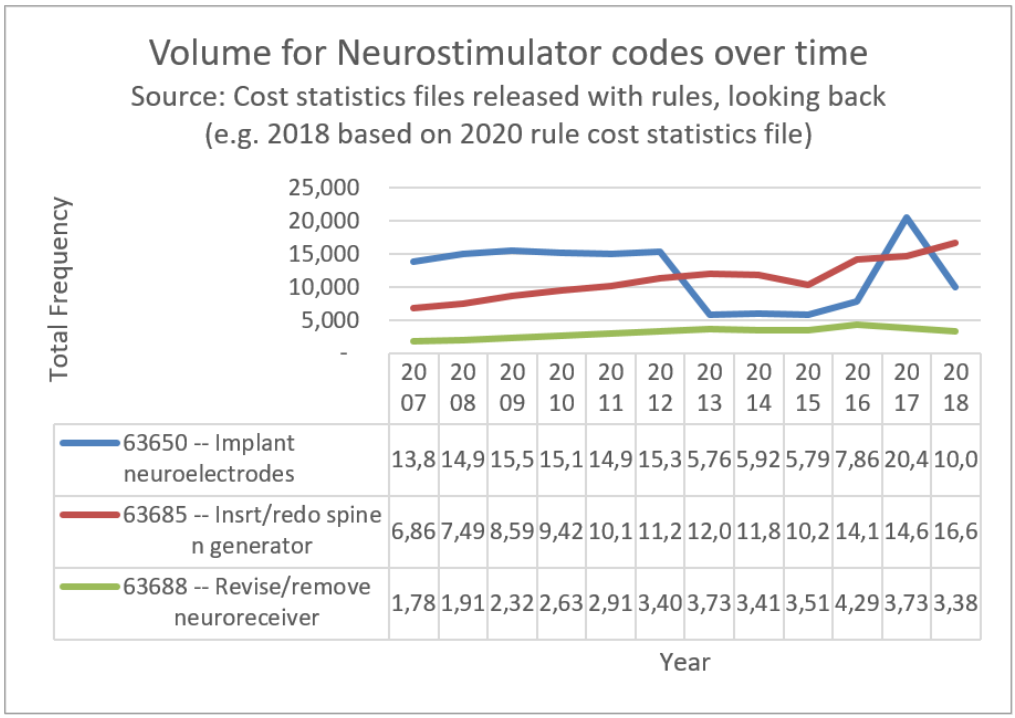
Implanted Spinal Neurostimulators. A spinal cord stimulator (SCC) is an implanted device that sends low levels of electricity directly into the spinal cord to relieve pain. SCSs can be used to treat a variety of diseases that result in chronic pain. The most common indications include failed back surgery syndrome (FBSS) with radicular pain, complex regional pain syndrome (CRPS), peripheral neuropathy, phantom limb pain, angina, and ischemic limb pain.[31] Other FDA approved indications include multiple sclerosis, postherpetic neuralgia, post-thorocotomy pain, intercostal neuralgia and spinal cord injuries.[32]

CMS reports that claims data for the 12-year period from 2007 through 2018 show increases in volume for implanted spinal neurostimulator codes, including: CPT code

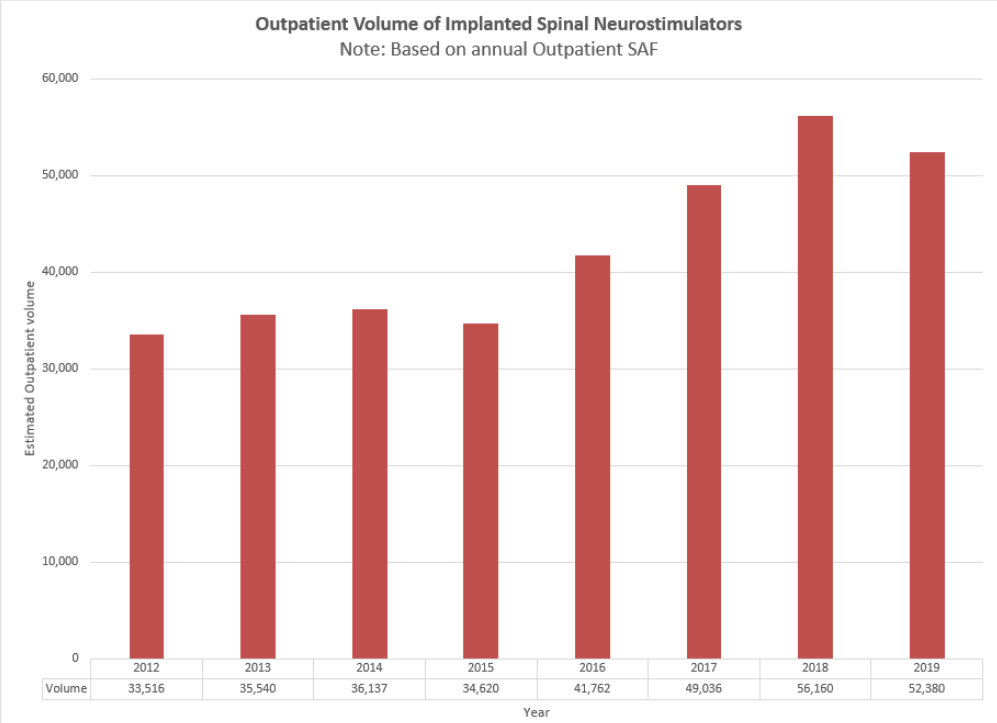
[28] *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1511 (D.C. Cir. 1984).
[29] *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 185 (D.C. Cir. 2011).
[30] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).
[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3389317/.
[32] https://emedicine.medscape.com/article/1980819-overview#a3.

63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver; CPT code 63688 Revision or removal of implanted spinal neurostimulator pulse generator or receiver and CPT code 63650 Implantation of spinal neurostimulator electrodes, accessed through the skin. While the agency notes average increases in volume over this entire time period, it also stresses the significantly higher average annual increase in volume of 17% for CPT code 63685 for 2016 through 2018.

In the charts below, the AHA displays the volume trend for each CPT code over time as well as a chart showing the combined volume of all three implanted neurostimulator codes over time. These charts show relatively flat volumes through 2015, with significant increases in volume for 2016 through 2018.



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
63650 -- Implant neuroelectrodes	13,8	14,9	15,5	15,1	14,9	15,3	5,76	5,92	5,79	7,86	20,4	10,0
63685 -- Insrt/redo spine n generator	6,86	7,49	8,59	9,42	10,1	11,2	12,0	11,8	10,2	14,1	14,6	16,6
63688 -- Revise/remove neuroreceiver	1,78	1,91	2,32	2,63	2,91	3,40	3,73	3,41	3,51	4,29	3,73	3,38



This increase in the utilization of these implanted spinal neurostimulators can be explained by the national focus on the opioid crisis and the subsequent efforts by the Administration and its multiple federal agencies to address the crisis. For instance:

- In January 2017, CMS issued its Opioid Misuse Strategy, with the mission to impact the national opioid misuse epidemic by, among other things, increasing the use of evidence-based practices for acute and chronic pain management, including encourage the use of non-pharmacologic therapies, non-opioid pharmaceuticals, and multi-modal analgesia as first options for pain management.

- In October 2017, the Secretary of HHS declared the opioid crisis to be a national PHE under federal law.

- In November 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis (Commission) issued a report that, among many other recommendations, requested that "CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain."

In CMS's CY 2019 OPPS/ASC rulemaking, in response to the Commission's request, CMS finalized a new policy to un-package and pay separately for non-opioid pain management drugs that function as surgical supplies (initially just Exparel) when they are furnished in the ASC setting for 2019. While the agency declined to pay separately for these drugs in hospital outpatient departments, it noted that it would continue to analyze the issue of access to non-opioid alternatives.

CMS also indicated in the 2019 proposed rule that it was interested in evidence relating to products that have shown clinical improvement over other alternatives, such as devices that have been shown to provide a substantial clinical benefit over the standard of care for pain management. The agency noted as an example "spinal cord stimulators used to treat chronic pain," which CMS hinted could be proposed for separate payment (rather than packaged payment) if sufficient evidence were presented. In response, several manufacturers of SCCs commented that separate payment was warranted for such devices because they provide an alternative treatment option to opioids for patients with chronic, leg or back pain. Some manufacturers provided studies asserting that patients treated with their devices had decreased opioid use. In response, CMS noted that it would take these comments into consideration for future rulemaking and encouraged providers to use effective alternatives to opioid prescriptions when medically necessary.

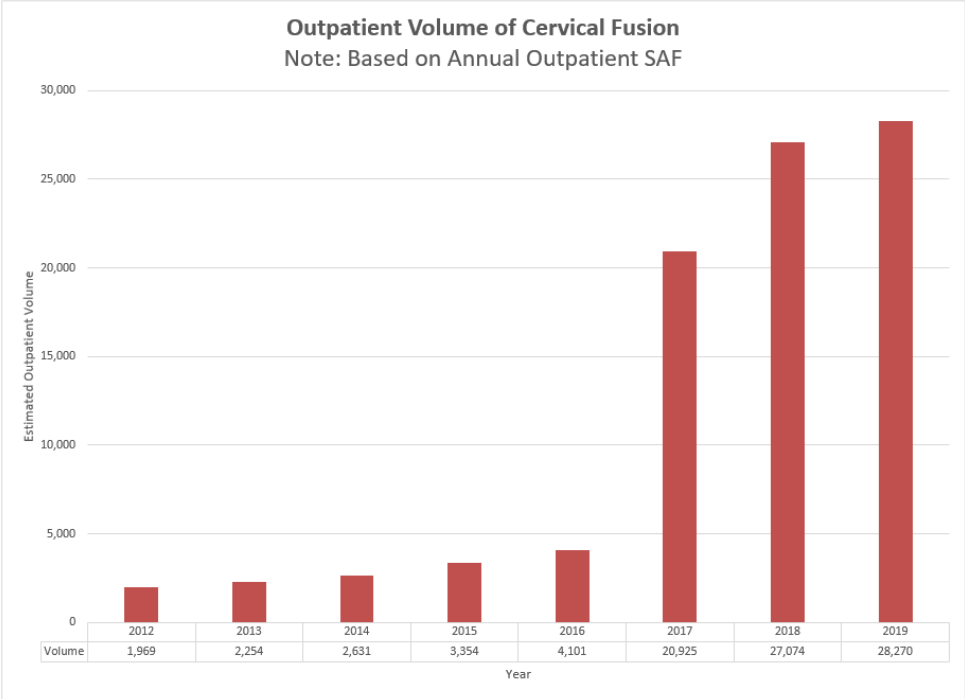
Thus, intense national focus on reducing the use of opioids in medical and surgical care caused a nationwide focus on substituting the use of non-opioid pain management treatments and technologies to address pain. This is a reasonable explanation for the increased utilization of implanted neurostimulators, which are indicated for the treatment of chronic pain. Therefore, we urge CMS not to finalize its proposal to add the three implanted neurostimulator codes to it prior authorization list.

Cervical Fusion with Disc Removal. This is a surgery to remove a herniated or degenerative disc in the neck. The indications for these procedures include cervical spine trauma and resulting instability, radiculopathy, myelopathy, osteomyelitis, spondylosis, vertebral body tumors, opacified posterior longitudinal ligament and postlaminectomy kyphosis.

In the proposed rule, CMS reports that claims data for a seven-year period, from 2012 through 2018 for cervical fusion with disc removal (codes CPT codes 22551 and 22552 (an add-on code)) show a "substantially greater increase than the 2.8% average annual increase for all OPD services over the same period." The agency focuses especially on a "dramatic" increase in volume between 2016 and 2018. In the chart below, the AHA displays the volume trend for the Cervical Fusion CPT codes over time.

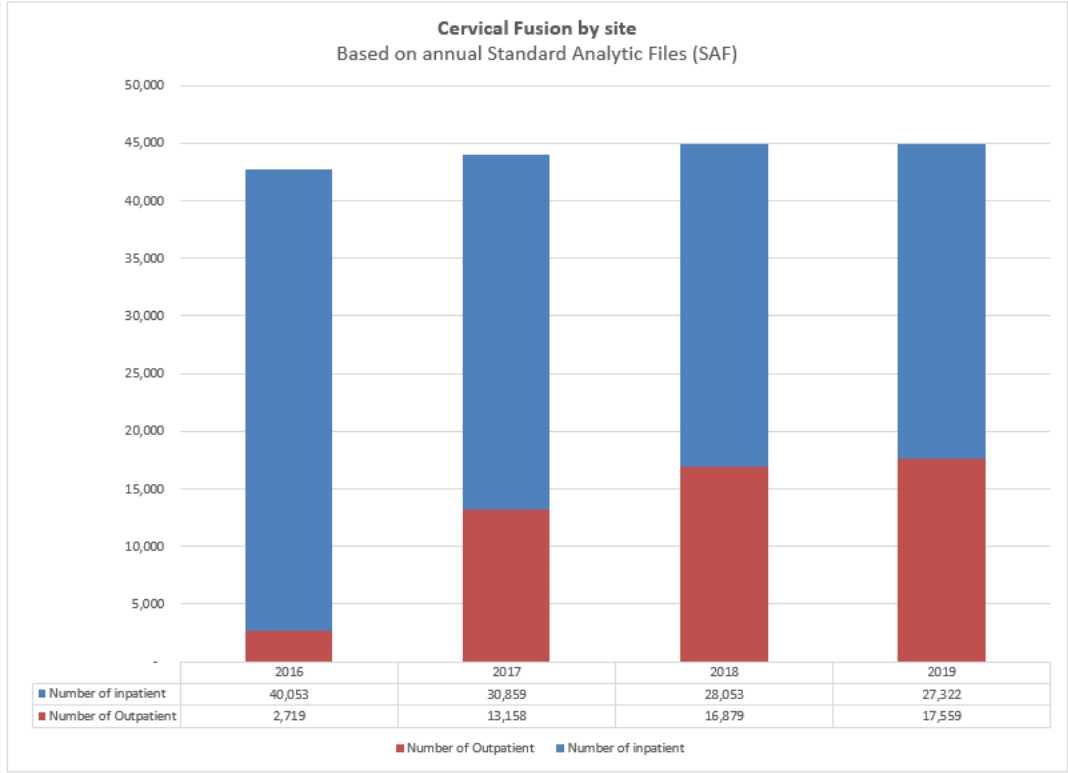
The agency suggests that this volume increase is due to the change in the APC assignment for CPT 22551 and 22552, in which these two codes were moved to a

higher level APC 0425, which increased the reimbursement rate, thereby creating a financial motivation for an unnecessary increase in utilization of these codes.



The AHA disagrees. Instead, the outpatient increases in the volume of these services is clearly due to the shifting of these services from inpatient to outpatient settings. In the proposed rule, CMS notes that the use of CPT 22551 "almost tripled in 2012 and significantly increased each year thereafter." Indeed, 2012 is the exact year that CPT 22551 was removed from the IPO list. In CY 2016, CPT 22552 also was removed from the IPO list and is part of a complexity adjustment for the comprehensive APCs.

In the chart below, the AHA demonstrates that there has not, in fact, been a significant overall increase in volume of these services in hospitals. Rather, with the removal of these procedures from the IPO list, the volume of procedures previously furnished in the inpatient setting shifted to the outpatient setting. This is not unnecessary. It is, in fact, the expected result when CMS removes services from the IPO list. Therefore, we urge CMS not to finalize its proposal to add the two cervical fusion with disc removal codes to it prior authorization list.



Given these shortcomings in CMS's analysis, we strongly encourage the agency to explicitly incorporate into its prior authorization methodology a review of whether an outpatient service showing a higher than average increase in volume has recently been removed from the IPO list. This recommendation is especially important in light of CMS's proposal to eliminate the IPO list over three years.