Illinois Health and Hospital Association

October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, D.C. 20201

Re: CMS-1736-P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (85 FR 48772)

Dear Ms. Verma:

On behalf of our more than 200 member hospitals and nearly 40 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on the calendar year (CY) 2021 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule. IHA commends the Centers for Medicare & Medicaid Services (CMS) for its thorough analysis in the development of this rule, and we value the administration's collaboration as we work to ensure the provision of effective and quality healthcare for all Illinoisans. This is particularly true as hospitals across the country, including in Illinois, continue to work on the front lines to maintain the safety of our communities as the COVID-19 public health emergency (PHE) persists. Our member hospitals and health systems require continued flexibilities and financial support not only during the PHE, but also long after it is over as healthcare providers join other industries across the country in rebuilding from the economic devastation that has accompanied and exacerbated the tragic health toll this virus has exacted on all Americans.

Given the issues and challenges that our hospitals are confronting at this time, IHA thanks CMS for the opportunity to make the following suggestions regarding certain proposals under consideration for the CY 2021 OPPS final rule. Specifically, we urge CMS to consider the following recommendations:

- Finalize the change in minimum required supervision level from direct to general for non-surgical extended duration therapeutic services;
- Immediately reinstate a 340B payment policy of average sales price plus 6%, bringing 340B payments in line with other Medicare drug payment policies;
- Reconsider proposed arduous prior authorization policies, particularly those for implanted spinal neurostimulator services, as increased use of such services

coincides directly with the opioid PHE that our hospitals are addressing in tandem with COVID-19;
- Finalize proposed changes to the Overall Star Ratings, recognizing that proposed changes are meaningful initial attempts at addressing the inadequacies of these benchmarks; and
- Reassess the appropriateness of discontinuing the inpatient only list, particularly on the proposed tight 3-year timeframe.

Detailed comments follow.

Changes to Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs

Just as in CY 2020, we strongly support CMS' proposal to improve beneficiary access to outpatient therapeutic services by changing minimum required supervision levels. Under the CY 2020 OPPS final rule, CMS changed the minimum required supervision level from direct to general supervision for most outpatient therapeutic services. Building on this progress, we support CMS' proposal to change the minimum level of required supervision to general for all non-surgical extended duration therapeutic services (NSEDTS) beginning Jan. 1, 2021.

Similarly, we support CMS' proposal to allow for direct supervision of pulmonary, cardiac, and intensive cardiac rehabilitation services via audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We agree that such a change is not only necessary during the PHE to protect clinicians and patients, but logical moving forward as it allows better access to these rehabilitation services for beneficiaries in underserved areas of our state.

These changes will positively impact access to and utilization of therapeutic services in our hospitals, particularly our rural hospitals which have expressed difficulty in meeting direct supervision requirements for years.

340B Medicare Payment

Congress created the 340B program to protect certain clinics and hospitals (hereinafter referred to as 340B hospitals) from drug price increases and give them access to price reductions. 340B hospitals have disproportionate share rates above 11.75%, meaning such hospitals serve a significantly disproportionate number of low-income patients compared to non-340B hospitals. 340B hospitals may dispense discounted drugs to any patient, regardless of payer, and retain the difference between the reduced price paid for the drug and the full reimbursement amount. According to the Health Resources & Services Administration (HRSA), this arrangement allows 340B hospitals to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

In Illinois, 340B hospitals have an average disproportionate share percentage above 40%. These hospitals use 340B savings to provide direct access to healthcare services and medicines for patients who cannot typically afford such care, as well as to support a variety of programs that increase access to healthcare services in their communities. For example, one of our hospitals uses 340B savings to help fund a mobile clinic program that brings healthcare services directly to low-income and underserved communities, such as providing school physicals for those in low-income neighborhoods, regardless of a family's ability to pay. Other Illinois hospitals use 340B savings to provide free colonoscopies and mammograms, free transportation, mobile dental vans, and other services that work toward narrowing health disparities and improving equity in healthcare access. Maintaining access to these critical healthcare services for our most vulnerable patients and communities is challenging, and that is why we continue to disagree with CMS' decision to decrease payment for 340B-acquired drugs.

In this proposed rule, CMS proposes two reimbursement options: (1) Average Sales Price (ASP) minus 34.7% plus a 6% add-on payment and (2) ASP minus 22.5%, the current reimbursement policy. In our view, neither option is sufficient in terms of complying with the intent of the 340B program, as both threaten the 340B system and the vulnerable Americans who rely on it.

Regarding the first option, ASP minus 34.7% plus 6%, CMS based this proposal on the results of a recently fielded acquisition cost survey. CMS asked 340B hospitals to respond to this survey during the first surge of COVID-19 in the United States. Given that hospitals, particularly urban hospitals, were undeniably preoccupied with confronting COVID-19, 55% of surveyed hospitals chose to answer the survey by relying on price data from HRSA, and 38% chose not to respond at all. Only seven percent of surveyed hospitals provided a detailed survey response. These raw data yielded a range of average acquisition costs between 58% and 78% of ASP. CMS states it arrived at ASP minus 34.7% by volume weighting survey data to account for actual drug usage under the OPPS, addressing HCPCS codes with multiple National Drug Codes, and accounting for outliers. The 6% add-on payment reflects the assumed overhead and other administrative costs of drugs paid for under other Medicare payment systems, such as the Medicare physician fee schedule.

While CMS clearly analyzed the available data as best it could, the reader has no basis for determining the validity of CMS' analysis as there is little transparency regarding the representativeness of the detailed survey responses compared to 340B hospitals as a group. Further, HRSA collects 340B ceiling prices, and CMS stated they imputed 340B ceiling prices for those hospitals that did not respond. CMS states that using ceiling prices skews the data toward a minimum average discount. In other words, the proposed policy of ASP minus 34.7% is based on skewed data from 93% of 340B hospitals. Even if this result is somehow favoring 340B hospitals, it is simply bad policy to project an overwhelmingly flawed analysis onto an entire program.

Further, the legality of these proposed payment changes remains under legal question. In Dec. 2018, the U.S. District Court in D.C. ruled against the U.S. Department of Health and Human

Services (HHS) in *American Hospital Association, et al. v. Azar, et al.*, indicating CMS' price cut was not legal. Though the D.C. Circuit Court of Appeals reversed this ruling in July, legal arguments are far from settled. The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs asked the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the decision. CMS should await the final legal decision before moving forward with any payment reduction, particularly when one of the original appellate panel judges vehemently dissented from the July decision.

Thus, we also disagree with CMS' proposed alternative to continue the current 340B payment policy of ASP minus 22.5%. We continue to implore HHS to follow OPPS statute, which requires HHS to reimburse hospitals for covered outpatient drugs at ASP plus 6%. While HHS has some authority to deviate from this policy, HHS has not demonstrated that these proposed 340B payment changes are in an effort to more accurately and fairly implement the statutory default rate of ASP plus 6%. Instead, HHS is clearly moving against Congressional intent to operate a program that fiscally supports clinics and hospitals that treat a disproportionate number of low-income patients.

CMS should immediately reinstate the 340B payment policy of ASP plus 6%. Hospitals and patients across the country depend on this program, particularly in the face of COVID-19, a disease that continues to disproportionately impact Americans of color and lower socioeconomic status.

Addition of Service Categories to the Hospital Outpatient Department Prior Authorization Process

IHA recognizes that the HHS Secretary has the authority under section 1833(t)(2)(F) of the Social Security Act to develop "a method for controlling unnecessary increases in the volume of covered OPD services" (84 FR 61142, November 12, 2019). Under this authority, CMS created a prior authorization process in the CY 2020 OPPS final rule, subjecting specific service categories to prior authorization (PA) requirements including: Blepharoplasty, Botulinum toxin injections, Panniculectomy, Rhinoplasty, and Vein ablation. However, we argue that CMS fails to demonstrate that the increase in utilization of these OPD service categories is inappropriate.

Additionally, based on recent communication with National Government Services (NGS), the predominant Medicare Administrative Contractor (MAC) among Illinois hospitals, several providers are experiencing difficulty submitting claims subject to this prior authorization process. Specifically, NGS reported the following issues:

- Botulinum toxin injections claims are missing site and frequency of the injections from documentation;
- Blepharoplasty claims are missing visual files, photos or initial patient complaints;

- Panniculectomy claims are denied because conservative treatment was given to the patient prior to the doctors making incision; and
- Vein ablation claims are denied because conservative treatment was given to the patient prior in testing in regard to the location and level of toxicity.

These issues point to two issues: first, there has not been adequate education or lead-up time to the changes required to comply with this prior authorization process. Illinois hospitals are not unfamiliar with prior authorization requirements, and managed care organizations operating in the state are prone to using them. And yet, even with significant experience with such a process, our hospitals experience thousands of prior authorization-related claim denials per week. Second, the source of the problem is often the ordering physician.

As suggested in comments made on the CY 2020 OPPS proposed rule, CMS had other options regarding unnecessary increases in outpatient services that should be explored before turning to a burdensome prior authorization process. Specifically, CMS could develop national coverage determinations (NCDs) or encourage MACs to develop additional local coverage determinations (LCDs) for procedures with concerning increases in utilization. Additionally, CMS could instruct MACs to conduct Target, Probe, Educate (TBE) programs to help providers reduce claim denials and appeals.

Both of these options are still viable moving forward. In fact, even if CMS does finalize the inclusion of implanted spinal neurostimulators and cervical fusion with disc removal service categories as part of the prior authorization program, they should revisit the implementation date, providing more than six months for providers to make necessary changes. MACs should provide TBE in an effort to curtail the potential number of denied, but medically necessary, claims once these new service categories are added to the mix.

This is particularly true for the Implanted Spinal Neurostimulator service category. CMS looked at outpatient department claims from 2007 through 2018, noting particular increases in implanted spinal neurostimulators between 2016 and 2018. These years coincide with the nation's heightened scrutiny of opioid use and misuse, aligning with the Administration's classification of the opioid crisis as a national public health emergency. Further, during this same time period, spinal cord stimulators were found to be a safer non-opioid pain management service for certain patients.[1,2] Considering Medicare-eligible adults experienced the largest increase in prescription opioid overdose deaths of all age groups at 10.5% from 2016 to 2017,[3] it is logical that physicians would attempt to find alternative solutions to pain management, rather than turning to opioids for Medicare patients. To put burdensome impediments such as prior authorization requirements on such services when other, more appropriate medical necessity checks are available, seems counterintuitive to stemming the opioid PHE and contrary to the Patients over Paperwork initiative of this Administration.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6686020/
[2] https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation
[3] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00309

CMS' prior authorization process punishes the hospital for the actions of physicians, who may require additional education and lead-up time to implement CMS' new policy. It is imperative that physicians and hospitals work together to optimize outcomes for patients, and this policy pits these two entities against each other. Furthermore, it does not make sense to hold one actor financially responsible for the other. Thus, we request that CMS reexamine its use of this prior authorization process. We also request that CMS provide better evidence for the inclusion of implanted spinal neurostimulator services on the prior authorization process list, as it appears increased utilization of such services is ultimately at the request of this Administration that is relying on healthcare providers to fix an opioid crisis caused by a multitude of complex factors.

Hospital Overall Star Ratings

Overall, we support CMS' proposed changes to the Overall Star Ratings, and view these changes as important initial steps in creating a more meaningful system for patients and providers. We agree that the proposed changes achieve the stated goals of increased methodological simplicity, measure predictability over time, and comparability of ratings among hospitals.

Regarding inclusion of Critical Access Hospitals (CAHs) in the Overall Star Ratings, we support CMS' proposal to include voluntary measure data from CAHs for the calculation of Overall Star Rating through authority in section 1704 of the Public Health Service Act (PHSA). We recognize and agree that including CAHs in the Overall Star Ratings when data are available is important in pursuing healthcare transparency, consumer choice, and increasing information availability on hospital quality. So long as CMS maintains the option for CAHs to opt out of publicly reporting their data, and thus not be included in the Overall Star Ratings, we agree that inclusion of CAHs in the rating system is a positive change.

Further, we support CMS' proposal to publish the Overall Star Ratings once annually, and agree with the justification for using publicly reported data from a quarter within the prior year. We thank CMS for considering that hospitals would appreciate and utilize additional time to review and potentially correct the measures that make up their Overall Star Rating. Additionally, we agree that publishing data once annually will mitigate statistical noise that may affect measures quarter-by-quarter.

We commend CMS' proposal to move away from latent variable modeling. While there are issues with using a simple average for measure scores, we agree that the proposed methodology is a good first step in creating a system that is easier to understand, communicate and replicate. Similarly, CMS' proposal to standardize measure group scores prior to combining measure groups is also a good step toward creating a more comprehensible system. We urge CMS to continue working with stakeholder groups to refine the Hospital Star Ratings moving forward. We view these changes as a work in progress, rather than a finalized methodology to use indefinitely.

Regarding CMS' proposed stratification of the readmission measure group score by hospitals' proportion of dual-eligible patients, we support appreciate that CMS is better aligning the Hospital Readmission Reduction Program with the Overall Star Ratings. We also believe that stratification by proportion of dual-eligible patients is appropriate as CMS begins addressing longstanding concerns that measures, and particularly readmission measures, do not adequately reflect differences in patient population across hospitals. We urge CMS to view this proposal as a transitional strategy, and again suggest CMS work with stakeholder groups to develop more sophisticated approaches to account for risk factors impacting patient readmission. Additionally, we ask CMS to consider implementing risk stratification in calculating other measures within the Overall Star Ratings. Dual eligibility is not the only risk factor potentially affecting readmission numbers. We are happy to engage with CMS to further refine their approach to account for issues that are outside the hospitals' control when it comes to all measures making up the Overall Star Ratings.

Finally, we applaud CMS' attempt to improve the comparability of hospitals through the proposed peer grouping of hospitals based on the number of measure groups submitted. This is a complex undertaking, and CMS' proposal is thoughtful and well researched. We remain concerned that grouping hospitals based on the number of measure groups submitted may not be an exhaustive approach to improving hospital comparability. While CMS did extensive analysis to understand the types of hospitals that submit three, four, and five measure groups, there are significant challenges in this approach. For example, CMS found that most three measure group submissions seldom report Safety of Care or Patient Experience, two measure groups that are particularly important to patients. Further, it is not clear how peer grouping hospitals will help a patient compare an academic or teaching hospital (often in the five measure group category according to CMS) with a safety net hospital (which would be in the three or four measure group categories). Two such hospitals may be in close geographic proximity, and providing patients with a means of comparing those hospitals would be ideal. Thus, we ask CMS to continue down this path of improving the Overall Star Ratings and making comparability more exhaustive and meaningful.

Removing the Inpatient Only List (IPO)

In the CY 2000 OPPS final rule, CMS stated "we believe that certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, indisputably require inpatient care, and therefore are outside the scope of outpatient services. Certain other procedures that we proposed as "inpatient only" may not be so clearly classified as such, but they are performed virtually always on an inpatient basis for the Medicare population."

Today, CMS proposes removing the Inpatient Only (IPO) list, suggesting that advances in medical knowledge and technology make the list moot.

We agree that medical knowledge and technology advanced significantly over the past two decades, and that some services currently on the IPO list, particularly those that CMS originally indicated may not clearly appear to require inpatient care, could be removed with site of service left to the physician. However, we ask CMS to consider those surgically invasive procedures that originally prompted the creation of the IPO list. One effect of the IPO list is reduced administrative burden for both CMS and hospitals in that they do not have to contend with the creation and administration of two PPS for the same procedure. As CMS states, doing away with the IPO list will require providers to adjust to the removal of procedures, update their billing systems, and gain experience with new billing practices. This seems unnecessary for those procedures that truly only occur in an inpatient setting. Instead of doing away with the IPO list altogether and creating unnecessary duplicative administrative tasks, we ask CMS to instead strengthen their criteria for remaining on the IPO list, making the list more exclusive and a better representation of changes to place of service and medical technological abilities.

Further, CMS proposed phasing in the removal of the IPO list over three years. The financial impact of a major shift in place of service for these procedures, assuming many of them will end up on the ASC-covered list, could be catastrophic for our hospitals at this time. The timing of this proposal could not be worse considering the ongoing and likely long-term negative financial impact of COVID-19. CMS may argue that there will never be an ideal time to introduce such a major change to hospital activities and finances; however, given this dramatic change and the numerous other regulatory and financial changes that hospitals are dealing with during the global pandemic, the removal of the IPO list should be postponed. At minimum, we request that CMS delay this proposal until at least two years after the end of the COVID-19 PHE, keeping in mind that while our front line heroes continue to battle COVID-19, they are also starting to plan for the next public health crisis that America's scientific community urgently warns is on its way.

IHA thanks CMS for proposing to extend the two calendar year exemption of services removed from the IPO list from site-of-service claim denials, BFCC-QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for "patient status." We ask CMS to clarify the process in such cases when a physician believes a procedure warrants inpatient care, but the patient does not meet the two-midnight rule and is instead discharged "early." In such cases, the physician will have exercised her or his judgment to provide the procedure as an inpatient service per this rule, but will have simultaneously violated the two-midnight rule. What ramifications will the provider face in such cases? We propose that in such cases, the grace period remain in place indefinitely until CMS has sufficient evidence that procedures removed from the IPO list are routinely and safely performed in the outpatient setting, ideally with claims evidence from several payers (i.e., Medicare, commercial payers, Veterans Affairs hospitals, etc.). The simple fact is that some of the procedures that are currently on the IPO list will never be performed in an outpatient setting. Again, removing the IPO list entirely is simply creating administrative and procedural hurdles for both CMS and providers.

Finally, 60 days is simply not enough time to review the current IPO list and provide meaningful comment on the 266 musculoskeletal-related services that CMS proposes removing in CY 2021, nor the remaining services that CMS would like removed by CY 2024. Given the plethora of moving parts related to COVID-19, it is unreasonable for CMS to request such a review at this time. CMS should, at a minimum, delay this proposal until after the COVID-19 PHE ends.

Ms. Verma, thank you again for the opportunity to comment on this proposed rule.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association