Sept. 20, 2019

Ms. Seema Verma D R A F T

Administrator

Centers for Medicare & Medicaid Services

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Room 445-G

Washington, DC 20201

Comments submitted electronically at <http://www.regulations.gov>

**File Code: CMS–1716-P - Medicare Program: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; 2020 Proposed Rule**

Dear Ms. Verma:

On behalf of its member hospitals, the Michigan Health & Hospital Association (MHA) appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to update the Medicare Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems effective Jan. 1, 2020. As proposed, this rule is projected to increase Medicare fee-for-service (FFS) OPPS payments to Michigan hospitals by an estimated $18 million, or 0.8%, significantly less than the projected 5.5% to 7% increase in healthcare inflation for 2020. This net impact includes the estimated $21 million payment cut when all clinic visits provided at off-campus hospital outpatient departments (HOPDs) are paid at 40% of the OPPS rate, regardless of the facility’s grandfathered status down from the current 70% of the OPPS rate.These cuts continue to threaten the financial viability of hospitals as they strive to provide services to Medicare beneficiaries in locations that better meet the needs of their patients.In addition, hospitals continue to be subject to the impact of the 2% payment sequestration reduction which is a $42 million annual cut to Medicare FFS OPPS payments.

The MHA remains extremely concerned about the future of the Medicare FFS OPPS since the gap between the cost of providing services and OPPS payment rates continues to increase. The Medicare OPPS proposed rule includes a market basket increase of 2.64%, which would result in a $55 million increase to Michigan’s FFS OPPS payments estimated at $2.092 billion. However, in FY 2017 Medicare OPPS rates fell short of the cost to provide care to Michigan’s FFS enrollees by $340 million or 17% ***based on Medicare allowable costs.*** When cost increases from 2017 to 2020 are factored in, we anticipate the payment shortfall for Michigan’s hospitals to increase from $340 million. In addition, this does not represent the payment shortfall for services provided to Medicare Advantage (MA) enrollees (many of the MA plans utilize the Medicare OPPS fee screens) or for laboratory and therapy services which are not paid under OPPS.

An observation that is frequently made is that hospitals need to reduce their costs to improve their profitability on Medicare services. Based on a nationally recognized calculation for cost per case, which considers both inpatient and outpatient volume, Michigan’s hospital cost is 9.8% below the national average, which has remained approximately the same from 2013 to 2017. Having lower than average cost supports the fact that the negative margins on Medicare FFS OPPS services are not the result of high costs but rather inadequate payment levels.

Michigan hospitals can no longer sustain a $340 million loss providing services to Medicare FFS patients. Commercial insurers are unwilling to subsidize government underfunding and the CMS would not contract for services and accept payment that is 17% less than the CMS’ cost of providing the services. The CMS should not put hospitals in the position to do something that agency would be unwilling to do.

Nationally, the payment shortfall for OPPS FFS versus cost is $7.4 billion, or 12.6%. While we understand that the CMS may be reluctant to mitigate the entire OPPS loss in one year, which would require a market basket increase of 12.6%, we believe that a structured plan to eliminate the loss is the responsible action for the CMS to take to ensure that the nation’s hospitals remain financially viable to continue providing medical services to the increasing number of Medicare enrollees and the other patients we serve**. Therefore, the MHA recommends that the CMS adopt a five-year plan to eliminate the payment shortfall by providing a 4.7% market basket increase for 2020 and then adding 2% to the market basket for each of the subsequent four years. This is particularly critical as more and more services continue to shift from the inpatient to outpatient setting.**

The MHA’s comments focus on the CMS’ proposed changes for 2020 related to the following:

* requirements for hospitals to make a list of their standard charges and negotiated third party payment rates available
* continued phase-in of payment cuts for **all clinic visits** provided at off-campus hospital outpatient departments (HOPDs) from 70% to 40% of the OPPS rate, regardless of grandfathered status under Section 603 of the Bipartisan Budget Act of 2015 (BiBA)
* continuing 340B payment cuts
* revisions to the inpatient only list (IPO)
* addition of procedures to the ASC-covered list
* prior authorization process requirements for certain outpatient hospital department services
* cost reporting, maintenance of hospital chargemasters, and related Medicare payment issues
* changes to the hospital outpatient quality reporting (OQR) program

**TRANSPARENCY**

(*Federal Register* pages 39571 - 39594)

The MHA strongly supports healthcare transparency inclusive of both price and quality and believes regulatory changes to increase healthcare transparency should result in outcomes that meet the needs of patients to make informed healthcare purchasing decisions while not adding unnecessary burden and cost to healthcare providers and the healthcare system. **The MHA opposes new hospital price transparency changes outlined in the OPPS proposed rule and requests that the CMS abandon the proposal.**

The CMS proposes to update regulations implementing hospital price transparency requirements pursuant to section 2718(e) of the Public Health Service Act (PHSA), which requires each hospital operating within the United State for each year to establish, update and make public a list of standard charges for items and services provided by the hospital. In the FY 2015 inpatient PPS final rule, the CMS required hospitals to make public a list of their standard charges or policies for allowing the public to view the charges upon an inquiry. In the FY 2019 IPPS final rule, the CMS updated the guidance to require hospitals to make available their standard charges via the internet in a machine-readable format.

The CMS is now proposing additional changes that the MHA believes exceeds congressional intent and will not provide information patients desire to make informed healthcare purchasing decisions. Specifically, the CMS is proposing to:

1. Establish a definition for “payer-specific negotiated charges” as the “charge that the hospital has negotiated with a third-party payer for an item or service.” (p. 39579)
2. Require hospitals to make public in a machine-readable format “payer-specific negotiated charges” for a list of shoppable services.

The CMS lacks the legal authority to require hospitals to make publicly available payer-specific negotiated amounts. Section 2718(e) of the PHSA does not provide the CMS with authority to establish these requirements. The CMS’ proposal is contrary to the plain language of the statute, as negotiated charges are not “standard charges.” By definition, payer-specific negotiated amounts are not standard. The CMS’ proposed definition also violates the Administrative Procedure Act (APA) because it is unreasonable. In general usage, “standard” means “usual, common or customary.” Payer-specific negotiated charges are not usual, common or customary. They vary year by year, payer by payer and even health plan by health plan.

Under federal uniform billing requirements, hospitals must charge every patient the same amount for the same service regardless of the negotiated payment or government-derived payment amount. This is accomplished using the chargemaster. Gross charges included in the chargemaster should serve as the only definition for standard charges. As previously noted, hospitals are already required to post this information on the internet in a machine-readable format.

The patient out-of-pocket amount (copayment, coinsurance and/or deductible) is desired by patients to make informed healthcare purchasing decisions. Providers have a shared responsibility with others for improving the service-specific out-of-pocket information electronically available to patients on a timely basis.

Hospitals and other providers should be the principal source of patient-specific out-of-pocket amounts for patients who are uninsured. They are best positioned to determine if patients qualify for charity care or other discounts.

Third party payers should be the principal source of patient-specific out-of-pocket amounts for their members as they have the most accurate information on patient deductibles and remaining balances. They also have information regarding individual patients’ copayment and coinsurance amounts.

**The MHA encourages the CMS to establish a workgroup of health plans and hospitals to determine how to most accurately and efficiently provide patient-specific out-of-pocket amounts to their patients.**

Regulatory changes to increase healthcare transparency should result in outcomes that meet the needs of patients to make informed healthcare purchasing decisions while not adding unnecessary burden and cost to healthcare providers. Requiring hospitals to post payer-specific amounts would confuse many patients, not meet patients’ needs and add unnecessary cost to the system. In its comments, the MHA has made recommendations to improve healthcare transparency.

More work must be done to educate patients about how to use price and quality information together to make better informed healthcare decisions. The CMS is focusing its efforts in this proposal on price transparency. **The MHA recommends that the CMS also take action to promote the use of information about healthcare quality and patient safety**. The CMS provides this information to the public on its “provider compare” websites. This and similar sites such as the MHA’s transparency site, [www.verifymicare.org](http://www.verifymicare.org), should also be promoted.

**Payment Cuts for Off-Campus Clinic Visits**

(*Federal Register* page 39528)

The MHA recognizes the recent ruling by United States District Court Judge Rosemary Collyer who ruled in favor of hospitals in the December 2018 lawsuit filed by the American Hospital Association, the Association of American Medical Colleges, Mercy Health Muskegon and several other hospitals. The lawsuit was filed against the Department of Health and Human Services for finalizing a policy that phased-in over two years Medicare payment cuts for hospital outpatient clinic visit services provided at off-campus hospital outpatient departments (HOPDs) that were grandfathered under Section 603 of the Bipartisan Budget Act of 2015. **The MHA opposes these cuts which were contrary to the Congressional intent of Section 603 and the 21st Century Cures Act “mid-build” provision.**

As the Medicare population continues to increase and appropriate care is provided in the outpatient setting, patient volume in off-campus outpatient clinics will continue to increase. To better meet the needs of patients, many hospitals operate outpatient clinics in geographic areas that are closer in proximity and more convenient, particularly for the aging Medicare population that often faces transportation challenges. In the 2020 rule, the CMS proposed to continue its two-year phase-in of the payment cut for clinic visits provided at off-campus HOPDs to pay these visits at 40% of the OPPS payment rate down from the current 70%. Consistent with 2019, the CMS proposes implementing this cut in a nonbudget-neutral manner, which means that the CMS is reducing hospital OPPS payments by nearly $312 million nationally in 2020 following the $314 million cut in 2019.

**The MHA opposes this reduction as it is punitive to hospitals that operate offsite clinics which have improved access to these services. Michigan hospitals cannot sustain the estimated $21 million payment cut. Payment reductions of this magnitude will challenge hospitals to reassess the financial strength of all service lines, regardless of community needs. A hospital cannot maintain strong financial operations when a key area has such significant losses.**

In the final rule, t**he MHA urges the CMS to restore payments for clinic visits at grandfathered HOPDs to 100% of the OPPS rate. In addition, the MHA urges the CMS to make a lump sum payment to the facilities that were subject to the 2019 payment cut. We also request that no additional copayment be required from patients.**

**340(B) Drug Payment Cuts**

The MHA appreciates this opportunity to respond to the CMS request for comment on potential remedies.

Specifically, the CMS seeks potential remedies for the 2018 and 2019 payments and for use in 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals.

The MHA believes the remedy should be as follows:

**Refund payments should be made to each 340B hospital subject to the cuts and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 hospital OPPS rules, and others not adversely impacted by the reductions should be held harmless. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law**.

The Proper Remedy Is Straightforward and Easily Administered. We believe that this is a straightforward remedy that is easy to implement, will not be disruptive, does not require new rulemaking, and is comparable to those the courts and the CMS have adopted to correct other unlawful Medicare payment reductions. Specifically, the CMS can recalculate the payments due to 340B hospitals based on the statutory rate of average sales price (ASP) plus 6% provided by the 2017 OPPS rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount they are entitled to, including average sales price (ASP) plus 6% plus interest. Claims that have not yet been paid should be paid in the full amount, including ASP plus 6%.

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor — which will be uniform across hospitals — to determine how much should have been paid and thus how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest.

There Is Ample Precedent for Full Retroactive Adjustments that Are Not Budget Neutral.

There is ample authority for the Department of Health and Human Services (HHS) to remedy the underpayments caused by its unlawful rule, including: *Cape Cod Hospital v. Sebelius*, (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid), *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, (D.D.C. 2018), (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required), and *Shands Jacksonville Medical Center v. Burwell*, (D.D.C. 2015), (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6%).

The remedy does not need to be budget neutral. The authority the agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the CMS does not consistently apply budget neutrality to fix its missteps in other relevant instances. For example, the HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment when it made the error and it was not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the average sales price increases.

There Is No Basis for Paying Hospitals Less than the Statutory ASP Plus 6% The OPPS mandates that the HHS reimburse hospitals for covered outpatient drugs at ASP plus 6%. This was the methodology used from 2013 to 2017. HHS has now requested comment on adjusting the payment for 2018, 2019 and 2020 from ASP plus 6% to ASP plus 3%. Although the CMS has some authority to deviate from this law, the agency is attempting to use a policy rationale that is inconsistent with the law itself and, therefore, it would be unlawful to reduce ASP to 3%.

New Patient Co-Pays Are Not Required Medicare reimburses hospitals 80% for covered outpatient and the remaining 20% is collected from the patients or their secondary insurance. Since the HHS deviated from the lawful payment rate for 2018 and 2019 with a 30% reduction, in theory hospitals could collect from patients or their insurance companies the difference between 20% of the lawful payment rate and the 20% copay that was actually collected. The HHS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

Although the agency has raised the specter that a remedy would require patient co-pays to be adjusted retroactively, we do not believe that there is any law that would require hospitals to collect payments altered by the agency’s illegal act. Neither the False Claims nor anti-kickback statutes would apply since patients would not have been induced to seek services. Patients who reasonably believe that they have fully paid for hospital care provided months, or in some cases years, ago should not have to make these payments if hospitals are willing to forego them. Requiring patients to pay these additional amounts would result in much confusion for beneficiaries. In the final rule, w**e urge the HHS to clearly state that additional co-pays are not required from patients or their secondary insurers.**

**Proposed changes to the Inpatient Only List (IPO)**

(*Federal Register* pages 39523 - 39525)

The CMS is proposing to remove Total Hip Arthroplasty (THA), CPT Code 27130, from the Medicare Inpatient Only (IPO) list for 2020. This would allow the procedure to be performed as an outpatient surgery paid under the Medicare OPPS for patients who are healthy enough to not require an inpatient stay.

Hospitals are concerned that THA procedures for healthier patients will be shifted into an outpatient setting, leaving sicker, more costly patients to have their procedures performed in the inpatient setting. The “weight” for MS-DRG 470, like all MS-DRGs, is a blended historical average of all Medicare patients who have this procedure. Under the scenario described above, it will be approximately two years before MS-DRG weights are based on claims experience that incorporates this policy. In the interim, hospitals will be under-reimbursed for providing a medically necessary service to Medicare beneficiaries unless the CMS proactively adjusts the weight for MS-DRG 470 to reflect this policy shift.

In addition to repricing the MS-DRG itself, the CMS will need to account for this policy shift in lower extremity joint replacement (LEJR) episode target prices by adjusting for projected changes in the number of “outlier” cases, increased use of post-acute care sites of service, and a potential increase in readmissions rates for the patients who continue to have THA procedures performed in the inpatient setting. We believe that cases fitting the following criteria could be removed from the existing data set to determine the correct MS-DRG weight and episode pricing if the CMS opts to implement this policy:

1. Cases with no listed co-morbidities listed on the claim or that have a low-risk HCC score
2. A short length of stay (two days)
3. No institutional post-acute care utilization
4. No readmissions

Finally, if the CMS moves forward with this policy, we believe that the CMS will need to monitor and possibly adjust readmissions rates used in the Hospital Readmissions Reduction Program and posted on the Hospital Compare website. We are concerned that differential rates of adoption of performing LEJR procedures across and within regions could potentially skew readmission rates.

**Proposed Additions to the List of ASC-Covered Surgical Procedures**

The CMS proposes to add eight surgical procedures to the ASC-list making them eligible for payment in the ASC setting including:

* + Six coronary intervention procedures including: percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transcatheter placement of intracoronary stent(s)/drug-eluting intracoronary stent(s) with coronary angioplasty
	+ Total knee arthroplasty (TKA) procedure and mosaicplasty procedures

**The MHA urges the CMS not to finalize its proposal to add these procedures to the list of ASC-covered procedures since they may pose a safety risk to Medicare beneficiaries when performed in an ASC.** Given the compromised health of many Medicare patients, we urge the CMS to continue covering these procedures only in the hospital setting to mitigate risks and ensure that patients have immediate access to life-saving emergency and intensive care unit services.

**Proposed Prior Authorization Process Requirements for Certain Outpatient Hospital Department Services** (*Federal Register* pages 39603 - 39609)

Effective Jan. 1, 2020, the CMS proposes that providers must submit a prior authorization request for any service on its list of outpatient department services requiring prior authorization. The five categories of proposed services are: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

We believe that it is likely that the CMS will use a third-party authorization vendor for this process which will result in increased administrative burden on providers. **The MHA believes that the CMS can achieve its policy goal of eliminating accidental payment for cosmetic procedures, while minimizing the administrative burden, by developing a more robust National Coverage Determination rather than by requiring prior authorization. We encourage the CMS to work with the MACs to develop an NCD for the five categories of services.**

**Requests for Information (RFIs)**

(*Federal Register* page 39609)

The proposed rule includes two requests for information (RFIs) with the CMS seeking comments on:

Medicare Cost Reporting Processes and the Hospital Chargemaster

The Department of Health and Human Services is examining the relationship between the hospital chargemaster and Medicare cost report and the use of the chargemaster in setting Medicare payment rates. As part of this efforts, the CMS requests comment on:

* The continued value of the chargemaster charges in setting the hospital payment;
* The costs associated with maintaining the chargemaster for Medicare cost reporting and reimbursement;
* The potential to modernize or streamline the Medicare cost reporting process;
* The potential impact on submitting charge data to the CMS if the chargemaster were modified or replaced;
* Alternative sources that could provide the information necessary to calculate Medicare payments;
* The rationale for updating the chargemaster more frequently than on an annual basis; and
* The impact that more frequent updates could have on costs for patients.

The MHA recognizes that significant resources are required by hospitals for maintaining their chargemasters and believe that in general, an annual update is sufficient. We recognize though that due to the rapidly changing world of pharmaceuticals, supplies, etc., more frequent updates may be needed for some departments. In addition, payers other than Medicare, often rely on the hospital chargemaster which would likely be problematic if it were eliminated**. The MHA encourages the CMS to work with stakeholders to thoroughly vet any proposed elimination or replacement of the chargemaster. In addition, we urge the CMS to give hospitals a sufficient transition period to adapt to such changes.**

**Regarding the cost report, the MHA recommends that the CMS evaluate all worksheets of the Medicare cost report to determine their relevance in today’s environment. If a worksheet is no longer needed, we encourage the CMS to remove it from the cost report to streamline the cost reporting process and reduce the administrative burden on hospitals. Since many state Medicaid agencies and some other payers rely on data from the Medicare cost report, we encourage the CMS to compile a stakeholder workgroup prior to making major changes to the cost report.**

**Hospital Outpatient Quality Reporting (OQR) Program**

(*Federal Register* pages 39554 - 39561)

The Tax Relief and Health Care Act of 2006 required the CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual update to the OPPS payment rate. Hospitals that fail to report this data incur a reduction in their annual payment update factor of 2 percentage points.

The CMS proposes to remove one measure from the OQR program beginning with the 2022 payment determination and seeks comment on potentially adopting four patient safety measures previously adopted for ASCs.

Proposed Removal of OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases

The CMS proposes to remove this process measure from the OQR program beginning with the 2022 payment determination since the costs associated with the measure outweigh the benefit of its continued use in the program. Since its adoption, stakeholders, including the CMS, have identified concerns with the measure, including the CPT coding used to report the measure, the complicated measure exclusions, and the administrative burden of extensive, manual patient record reviews necessary to calculate measure performance. In addition, the CMS has proposed to remove this measure from the PPS-Exempt Cancer Hospital Quality Reporting Program. The measure steward is no longer maintaining the measure, so the CMS is no longer confident that it can ensure that the measure still aligns with clinical guidelines and standards.

If finalized, the measure would be removed beginning with October 2020 encounters, which impact 2022 OPPS payments. The CMS has indicated that this is the earliest that it could feasibly remove the measure since 2021 payments will be impacted by data collected during 2019. **Given the CMS’ concerns about this measure, the MHA supports the CMS’ proposed removal and encourages the CMS to do so as soon as possible.**

Comments Requested on Potential Future Adoption of ASC Patient Safety Measures

The CMS seeks comments on potentially adopting four patient safety measures for the hospital OQR program that were previously adopted for the ASC Quality Reporting Program (ASCQR) but are all currently suspended from use in the ASCQR program. These under consideration measures include:

* ASC-1: Patient Burn
* ASC-2: Patient Fall
* ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant
* ASC-4: All-cause Hospital Transfer/Readmission

These measures are currently included in the ASCQR program but data collection and reporting for these measures was suspended in 2019 due to concerns regarding the accuracy of the data used to calculate performance. In addition, each measure has lost endorsement by the National Quality Forum (NQF).

If the CMS were to propose these measures for adoption in the OQR program in the future, the agency potentially would do so with an updated submission method. Before the measures were suspended, ASCs were required to note “quality data codes” (QDCs) on Medicare claims in order to report these events, and at least 50% of claims meeting the individual measure’s specifications had to contain the correct QDC. In the 2019 OPPS/ASC proposed rule, the CMS expressed concern that this method “may impact the completeness and accuracy of the data.” Thus, to improve the completeness and accuracy of the data, the CMS would consider collecting data using a CMS online data submission tool, such as the QualityNet website currently used to report other quality measure data. In addition, CMS notes that these measures are currently specified for the ASC setting not the hospital outpatient setting.

**Consistent with our comments regarding measures proposed for use in other settings, the MHA remains opposed to the adoption of measures that do not have NQF endorsement for use in the specific setting. As a result, we oppose the future adoption of these four measures.** In addition, we have concerns regarding the data accuracy in calculating provider performance for these measures.

Again, the MHA appreciates this opportunity to provide input to the CMS. We believe that our suggested changes particularly those regarding the 340B cuts and additional payment cut for clinic visits provided at grandfathered off-campus HOPDs would more closely represent Congressional intent. In addition, our recommended changes would have a positive impact for hospitals and all patients they serve. Please contact me at 517-703-8608 or via email at vkunz@mha.org with any questions.

Sincerely,

Vickie R. Kunz

Senior Director, Health Finance