Sept. 20, 2018

Ms. Seema Verma

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–1695-P - Medicare Program: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; 2019 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, 2019. As proposed, this rule is projected to cut Medicare fee-for-service (FFS) OPPS payments to Michigan hospitals by an estimated $17 million, or 0.8 percent, in 2018. This impact includes the estimated $42 million payment cut when all clinic visits provided at off-campus hospital outpatient departments (HOPDs) are paid at 40 percent of the OPPS rate, regardless of the facility’s grandfathered status.These cuts will threaten the financial viability for hospitals to continue providing the necessary access and services to Medicare beneficiaries and other Michigan residents and further impede access to care for the most vulnerable patients.The estimated impact of the proposed rule excludes the continuing 2 percent payment sequestration reduction which is a $40 million annual cut to Medicare FFS OPPS payments.

Medicare FFS OPPS payment rates have historically failed to cover the cost of providing care. We believe the proposed payment cut will further jeopardize the financial viability of hospitals and impact their ability to provide critical services. The latest data available indicates that Medicare FFS OPPS payments are approximately 18 percent less than Medicare **allowable** cos, resulting in a payment shortfall of $356 million. Other payors and services must offset this payment shortfall.

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

* Payment cuts for **all clinic visits** provided at off-campus hospital outpatient departments (HOPDs) to 40 percent of the OPPS rate, regardless of the facilities’ grandfathered status under Section 603 of the Bipartisan Budget Act of 2015 (BiBA)
* Payment cuts for new families of clinical services provided in grandfathered off-campus HOPDs to 40 percent of the OPPS rate
* Expansion of the nearly 30 percent payment cut for drugs purchased through the 340B drug program and provided in non-grandfathered off-campus HOPDs
* Payment cuts for new drugs until average sales price data is available
* Proposed change to the packaging policy for drugs that function as a supply
* Hospital outpatient quality reporting program
* Addition of 12 procedures to the ASC-covered procedures list making them payable when provided in an ambulatory surgical center (ASC) setting
* CMS request for information on promoting electronic health record (EHR) interoperability and price transparency.

**Payment Cuts for Clinic Visits**

(Federal Register Pages 37,138 – 37,143 and 37,146 – 37,150)

Section 603 of the BiBA required, with limited exceptions, that services provided in an off-campus HOPD after Nov. 2, 2015, would not be paid under the Medicare OPPS, but instead would be paid under another applicable Part B payment system, which the CMS finalized as the Physician Fee Schedule (PFS). Under Section 603 of the BiBA, certain facilities were “grandfathered” and continued being paid under the Medicare OPPS including:

* Items and services provided in a dedicated emergency department (E/D)
* Items and services provided by an off-campus HOPD that met the following requirements:
  + The HOPD provided and submitted claims for covered services under the Medicare OPPS before Nov. 2, 2015;
  + The items and services are provided at the same location that the HOPD was providing such services as of Nov. 1, 2015;
  + The HOPD was determined to meet the 21st Century Cures Act “mid-build” provision.

For 2017, the CMS adopted the Medicare PFS as the applicable Part B payment system for non-grandfathered HOPDs and set payment rates at 50 percent of the Medicare OPPS payment rate. For non-grandfathered facilities for 2018, the CMS reduced this payment rate to 40 percent of the OPPS rate.

In the 2019 proposed rule, the CMS cites “unnecessary” increases in the volume of hospital outpatient clinic visits provided by off-campus HOPDs and proposes to pay for clinic visits provided in grandfathered off-campus HOPDs at the same rate they are paid in non-grandfathered off-campus HOPDs. It is unclear what data supports an “unnecessary” increase. As the Medicare population increases and appropriate care is provided in the outpatient setting, it makes sense that patient volumes in off-campus outpatient clinics would increase. Many of these hospital outpatient clinics are located in geographic locations closer to their patients increasing access for a population that often faces transportation challenges. For 2019, this “PFS-equivalent” payment rate is proposed to be 40 percent of the OPPS payment rate. The CMS proposes to implement this significant cut in a nonbudget-neutral manner, which means that it is estimated to cut hospital OPPS payments by $760 million nationally in 2019.

**The MHA opposes this reduction as it is punitive to hospitals that operate offsite clinics. Michigan hospitals cannot sustain the estimated $42 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.**

We believe that the CMS has misconstrued the Congressional intent with its proposal to cut payments for hospital clinic services provided at off-campus HOPDs which were grandfathered. In 2015, Congress intended to preserve the existing outpatient payment rate for grandfathered HOPDs in recognition of the critical role they play in their communities. The CMS’ proposal is counter to this and will impede access to care for the most vulnerable patients. This proposal also assumes that the care provided in the off-campus HOPD clinics is the same as that provided in a physician office**.** The proposed policy is punitive for hospitals that have opened additional physical locations and expanded their service mix to better address the needs of their patients. Along with the American Hospital Association (AHA) and others, **the MHA urges the CMS to continue paying the full OPPS rate for clinic visits provided at off-campus HOPDs that were grandfathered under Section 603 of the BiBA.**

**Expansion of Services at Grandfathered Off-Campus HOPDs**

(*Federal Register Pages 37,138 – 37,142 and 37,146 – 37,150)*

Based on the existing site-neutral payment policy, a grandfathered off-campus HOPD can expand the type of services it provides and receive the full OPPS payment rate for such services. This is an important provision given the ever-changing technologies and changing needs of patients particularly in rural communities. However, in the proposed rule, the CMS expresses concern that this policy incentivizes hospitals to purchase additional physician practices and add those physicians to an existing grandfathered off-campus HOPD, in a manner that the CMS believes is inconsistent with the intent of Section 603 of the BiBA.

For 2019, the CMS proposes that if a grandfathered off-campus HOPD begins to provide a new service from a clinical family that it did not previously provide and bill for during the baseline period (Nov. 1, 2014 to Nov. 1, 2015), the new service would no longer be a covered outpatient department service, Instead, the CMS would deem this to be a non-grandfathered service and pay at 40 percent of the OPPS rate. To implement this policy, the CMS proposes 19 groupings of clinical families of services and would require that as a condition of OPPS payment eligibility, grandfathered off-campus HOPDs ascertain the clinical families from which they provided services during the baseline period. The CMS has previously proposed this but ultimately withdrew a similar policy which penalizes HOPDs for expanding services to better meet the needs of their communities. As previously stated, hospitals continuously modify their operations and locations to better address the needs of patients. This proposal is punitive and will negatively impact the ability of hospitals to meet the needs of patients. **The MHA opposes this proposed change and urges the CMS not to move forward with this proposal and instead encourage hospitals to continue modifying locations and services offered to improve access to needed services.**

**340B Payment Reductions**

(*Federal Register* Pages 37,123, 137,125 – 37,126 and 37,143 – 37,146)

In 2018, the CMS finalized an OPPS policy that cut payment for separately payable drugs and biologicals acquired under the 340B drug discount program from ASP plus 6 percent to ASP minus 22.5 percent, resulting in a cut of nearly 30 percent**. The MHA, along with the AHA and others, continue to object to these payment cuts implemented in 2018 since they negatively impact facilities that provide services to the most vulnerable patients.**

In the proposed rule, the CMS expresses concern that the difference in payment amount for 340B acquired drugs provided in off-campus HOPDs, regardless of grandfathered status, creates an incentive for hospitals to remove drug administration services for these 340B-acquired drugs to non-grandfathered HOPDs to avoid the payment reduction. For 2019, the CMS proposes to pay for separately payable drugs and biologicals acquired under the 340B program at the rate of ASP minus 22.5 percent when they are provided by non-grandfathered HOPDs. The CMS proposes to exempt rural sole community hospitals, children’s hospitals or PPS-exempt cancer hospitals from these payment reductions, consistent with the 2018 cuts for 340B drugs. Nationally, the CMS has estimated that this change would result in a payment cut of $48.5 million in 2019. **The MHA opposes the CMS’ proposal to expand the Medicare Part B payment cuts to drugs acquired through the 340B drug pricing program provided at non-grandfathered off-campus HOPDs.**

**Payment Reduction for New Drugs Before Average Sales Price Data Are Available**

(*Federal Register Pages 37,111 – 37,117 and 37,121 – 37,126)*

Currently, Medicare pays new Part B drugs, those for which ASP data is unavailable under the first quarter of sales, at the rate of wholesale acquisition cost (WAC) plus 6 percent. Consistent with its proposal in the 2019 Physician Fee Schedule rule, the CMS proposes to reduce payment for new non-pass-through Part B drugs and biologicals (that are not acquired under the 340B program) to WAC plus 3 percent, rather than WAC plus 6 percent. This rate would apply during the time when the ASP data for the new drug are unavailable. This proposal is consistent with recommendations included in the fiscal year 2019 President’s Budget Proposal and MedPAC’s June 2017 report to Congress. The CMS notes this payment reduction would not apply to single source drugs that are required by law to be paid at 106 percent of the lesser of the ASP or WAC. Drugs and biologicals that are acquired under the 340B program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of WAC, as applicable**. The MHA urges the CMS to withdraw this proposal which would require hospitals to absorb the negative impact of these payment reductions rather than the pharmaceutical companies in their pricing of the drugs.**

**Proposed Change to Packaging Policy for Drugs that Function as a Supply**

*Federal Register Pages 37,111 – 37,117 and 37,121 – 37,126)*

Drugs that function as a supply are packaged under the OPPS and the ASC payment systems, regardless of the drug costs. For 2019, the CMS examined this policy in response to a recommendation in the President’s Commission on Combating Drug Addiction and the Opioid Crisis that the CMS review and modify rate setting policies that may encourage usage of non-packaged drugs—opioids— to obtain additional reimbursement for the drug. Given the emphasis nationally and in Michigan that has reduced opioid prescriptions, we believe the actions of hospitals have proven that this practice is not occurring.

The CMS evaluated utilization patterns for specific non-opioid drugs that function as a supply from 2013 to 2017 to determine whether the packaging policy has reduced the use of these drugs. For the majority of drugs, the CMS did not observe major utilization declines in the HOPD setting and observed the opposite effect for several drugs that function as a supply. However, the CMS’ finding in the ASC setting were different from the HOPD setting.

As a result, the CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are provided in the ASC setting for 2019. However, the CMS does not propose to pay separately for these drugs when they are provided in the HOPD setting. The CMS believes the proposed change will provide incentives to use non-opioid pain management drugs with surgical procedures in the ASC setting and is responsive to the Commission’s recommendation. **The MHA is appreciative of the CMS’ efforts to help reduce the use of opioids but urges the CMS to pay separately for the cost of non-opioid drugs in the hospital outpatient setting to maintain consistency in payment practices between similar settings.**

**Hospital Outpatient Quality Reporting Program**

(*Federal Register Pages 37,175 – 37,193)*

In the 2019 proposed rule, the CMS proposes to remove a total of ten measures from the outpatient quality reporting (OQR) program, with one measure removed starting with the 2020 payment year, which will be based on 2018 provider performance. Nine additional measures would be removed starting with the 2021 payment year, which is based on 2019 provider performance. The MHA is appreciative of the CMS proposal to remove measures that provided little to no value to patients. However, we remain concerned that several measures in the OQR program do not have or have lost endorsement by the National Quality Forum (NQF). **The MHA opposes the use of measures that are not endorsed by the NQF for use in that specific setting. We encourage the CMS to include NQF endorsement as a criterion for a measure’s inclusion in the OQR program, and assess measures for the impact of sociodemographic factors on performance and incorporate adjustments where needed.**

**Proposed Expansion of the Definition of “Surgery” for ASC-Covered Surgical Procedures**

(*Federal Register Pages 37,050)*

Since implementation of the ambulatory surgical center (ASC) payment system, the CMS has defined a surgical procedure as any procedure within the range of Category I CPT does that the AMA CPT Editorial Panel defined as surgery. The CMS also includes procedures described by Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that it determines do not pose a significant risk, would not be expected to require an overnight stay, and are separately paid under the OPPS.

Stakeholders have suggested that certain procedures outside the CPT surgical range that are similar to procedures already covered in the ASC setting should also be ASC-covered. In particular, some stakeholders have suggested adding certain cardiovascular procedures to the ASC-covered procedures list due to their similarity to currently covered peripheral endovascular procedures in the surgical code range.

In response, the CMS proposes to revise its definition of “surgery” in the ASC payment system to account for “surgery-like” procedures that are assigned codes outside the CPT surgical range. The CMS would define these newly-eligible “surgery like” procedures to be those procedures that are described by Category I CPT codes that are not in the surgical range but that directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. The addition of these Category I CPT codes would need to meet the ASC setting criteria—do not pose a significant risk, are not expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

For 2019, the CMS proposes to add 12 cardiac catheterization procedures (CPT codes 93451-93462) to the list of covered surgical procedures that the CMS believes could be safely performed in the ASC setting and not require an overnight stay. The CMS notes that although these procedures are similar to other procedures currently on the ASC list, and that they may be appropriately performed in an ASC. **Given the fragile medical condition of many Medicare patients and the comorbidities that many of them face, the MHA is concerned about the patient safety of performing these procedures in the ASC setting and urges the CMS not to add these 12 procedures to the list of ASC covered procedures**.

**Requests for Information (RFIs)**

In the proposed rule, the CMS includes two RFIs that it previously included in its fiscal year (FY) 2019 hospital inpatient PPS proposed rule. First, the CMS repeats its RFI on ways to promote interoperability by making changes to Medicare conditions of participation, conditions for coverage, and requirements for participation for long-term care facilities and post-acute care providers. Second, the CMS restates its RFI on ways to make more useful pricing information available to consumers.

**RFI -Promoting Electronic Health Record Interoperability**

(*Federal Register Pages 37,209 – 37,211)*

With this proposed rule, the CMS is issuing an RFI on “Promoting Interoperability and Electronic Health Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers”.

We support the CMS’ change of focus for the electronic health records (EHR) Incentive Program to reflect the continued importance of interoperability. Michigan has been a leader in statewide information sharing and the growth of Health Information Exchanges (HIEs) such as Great Lakes Health Connect ([www.GLHC.org](http://www.GLHC.org)) and the Upper Peninsula Health Information Exchange ([www.uphie.org](http://www.uphie.org)) is a reflection of that leadership.  Along with these HIEs, the Michigan Health Information Network ([www.mihin.org](http://www.mihin.org)) allows providers to “connect once” to gain access to patient information across the state. This network of networks facilitates interoperability and the exchange of electronic health information to build technical and collaborative partnerships between healthcare providers throughout the state; from hospitals and physicians to pharmacies and payers. MiHIN offers shared technology services that help ensure the electronic health records of Michigan citizens are available for all who deliver care services. More than 17 million secure patient information passes through MiHIN’s statewide network weekly.

In addition, the CMS seeks input regarding whether the agency should promote interoperability by including electronic sharing of health information as a Medicare condition of participation for hospitals, skilled-nursing facilities, inpatient rehabilitation facilities, and other post-acute care settings.

**Although the MHA is supportive of the CMS’ promoting interoperability, we object to the CMS requiring interoperability as a Medicare condition of participation since this would likely result in some hospitals and post-acute providers no longer being eligible to participate in the Medicare program and therefore would be ineligible for Medicare payments for services to Medicare beneficiaries, potentially resulting in hospital closures. Hospital closures or exclusion from Medicare would reduce access to essential services for Medicare patients. The MHA recommends that the CMS provide additional incentive payments to help ensure that hospitals and post-acute care facilities have the resources necessary for investing in technologies that promote interoperability.**

**RFI – Pricing Information**

(*Federal Register Pages 37,211 – 37,212)*

In the Medicare OPPS proposed rule, the CMS indicates it is considering potential actions that would be appropriate to further its objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including services that could be offered in more than one setting.

The MHA strongly supports healthcare transparency inclusive of both price and quality and is providing information in response to the CMS request for price transparency information. The MHA comments on price transparency follow. We believe the information outlined in these recommendations will improve healthcare transparency and provide patients with the information they desire.

**CMS Request**: How should we define “standard charges” in provider and supplier settings?  Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters?  Should “standard charges” be defined to mean:  average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list, or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together?  Should “standard charges” be defined and reported for both some measure of the average contracted rate and the chargemaster, price list, or charge list?  Or is the best measure of a provider’s or supplier’s standard charges its chargemaster, price list, or charge list?

**MHA Response**: Under federal uniform billing requirements, providers must charge every patient the same amount for the same service. The amount a provider or supplier charges prior to any discount (charity care, negotiated discount, etc.) should be the definition of standard charges. However, patients desire information on their out-of-pocket responsibility which is different by payer (Medicare, Medicaid, and commercial). The MHA recommends the CMS grant providers flexibility to provide patients the information they believe is appropriate for their market.

**CMS Request**: What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?

**MHA Response**: The patient out-of-pocket amount (copayment, coinsurance and/or deductible) is desired by patients to make informed healthcare purchasing decisions. In addition, when choosing a provider, patients have several other factors to consider including facility quality and patient safety, physician privileges, and access to services. We must collectively work to ensure patients understand that an inpatient stay or outpatient hospital visit may include services from multiple providers including a surgeon, hospital, and anesthesiologist, for example, each with their own bill and potential out-of-pocket payment requirements. Finally, we must work to ensure patients understand that new clinical information may be present during treatment that may impact the initial cost estimate. Below, we identify the best source for this information depending on the patient’s insurance status.

Providers have a shared responsibility with others for improving the service-specific out-of-pocket information electronically available to patients on a timely basis.

* 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. Providers can best enable patients to use charge information in their decision-making by posting charges on their websites with the following notations:
  + Uninsured patients should contact their provider to determine the standard charges and if they qualify for a discount from charges.
  + Insured patients should contact their insurer to determine their out-of-pocket amount.
* Medicare, Medicare Advantage, Medicaid, Medicaid managed care, and commercial insurers 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. While they may not have information for outstanding claims, it is still more complete than what individual providers have. Insurers also have provider payment rates to calculate the patient’s share of approved amount.

Michigan-based health plans have developed robust cost estimator tools that provide information based on member-specific copayment, coinsurance and deductible balances for various procedures and providers. Many health plans nationally have created similar tools for their members. 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.

**CMS Request**: Should providers and suppliers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service?  How can information on out-of-pocket costs be provided to better support patient choice and decision-making?  What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs?  How can CMS help beneficiaries to better understand how copayment and coinsurance are applied to each service covered by Medicare?  What can be done to better inform patients of their financial obligations?  Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

**MHA Response**: Providers have a shared responsibility with others for providing out-of-pocket information to patients who desire this information prior to receiving non-emergent services. For uninsured patients, providers should make available the out-of-pocket cost estimate. This includes working with patients to determine eligibility for financial discounts, providing information regarding other providers that may bill separately, and explaining that unforeseen circumstances may result in changes from the initial estimate. Providers should refer insured patients to their insurer as they have the most accurate information on deductible balances and provider payment rates to calculate the patient’s share of approved amount. In addition to working with providers, the MHA encourages the CMS to also work with insurers on healthcare price transparency.

**CMS Request**: Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier.  If so, what changes would need to be made by providers and suppliers.  What burden would be added as a result of such a requirement?

**MHA Response**: The CMS should not require providers to make available the amount Medicare pays for a particular service. As previously mentioned, the out-of-pocket amount is what patients desire. Adding a Medicare payment amount requirement would confuse many Medicare patients since it is not what they would pay for the service. In addition, in Michigan, as a result of our Medicaid expansion law, hospitals must already accept as payment in full 115 percent of Medicare rates from any uninsured individual whose income is at or below 250 percent of the federal poverty level. Instead, the MHA encourages the CMS to work with Medicare fee-for-service and Medicare Advantage plans provide patients with pre-service, patient-specific out-of-pocket estimates. No changes are required by providers if this mandate is not pursued.

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 organizations that do not have patient-specific information to provide patients with cost estimates will add unnecessary cost to the system while not meeting the needs of patients. In its comments, the MHA has made several recommendations to improve healthcare transparency.

We must continue to work collectively 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 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.

Finally, patients should also have information about total cost of care across the full continuum, professional, acute, and post-acute, to allow for a greater understanding of healthcare cost beyond an individual service.

Again, the MHA appreciates this opportunity to provide input to the CMS. We believe that our suggested changes regarding implementation the site neutral policy 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 517-703-8603 or via email at [mklein@mha.org](mailto:mklein@mha.org) with any questions.

Sincerely,

Marilyn Litka-Klein

Vice President, Health Finance

Policy and Health Delivery