Minnesota Hospital Association

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September 6, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Submitted electronically through www.regulations.gov.

RE: CMS-1656-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Payment to Certain Off-campus Outpatient Departments of a Provider; Proposed Rule (Vol. 81, No. 135), July 14, 2016.

Dear Mr. Slavitt:

On behalf of our 137 member hospitals and health systems, the Minnesota Hospital Association (MHA) appreciates the opportunity to comment on the provisions contained in the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2017 hospital outpatient prospective payment system (OPPS) proposed rule that would implement the site-neutral provisions of the Bipartisan Budget Act of 2015 (BiBA).

The hospital field and more than half of the U.S. House and Senate this spring urged CMS to provide reasonable flexibility when implementing the BiBA site-neutral provisions in order to ensure that Medicare patients have continued access to the highest quality hospital care in their communities. Instead, CMS has proposed a short-sighted and unworkable set of policies that provide no reimbursement to hospitals for the services they provide to Medicare beneficiaries. The agency's proposals would prevent us from being able to provide necessary, innovative and high-quality health care to our community and cannot be reasonably implemented. CMS must delay these site-neutral policies until it can adopt much-needed changes (outlined below) in order to provide fair and equitable payment to hospitals.

Payment Policy for Nonexcepted HOPDs. CMS proposes to make no payment to newer "nonexcepted" hospital outpatient departments (HOPDs) for the services they provide to Medicare beneficiaries in 2017. In other words, the agency would not provide any reimbursement to HOPDs for the nursing, laboratory, imaging, chemotherapy, surgical and many other reasonable and necessary services they provide to Medicare beneficiaries. Such a payment policy is completely

unreasonable and unsustainable. Many of our rural and urban hospitals provide access to some of the most vulnerable populations in their communities. Curtailing the provision of services that meet the needs of the community will stifle access.

We believe that the agency's basis for its "non-payment" policy is not sound. That is, CMS claims that the agency cannot pay hospitals directly under a non-OPPS Medicare Part B payment system in 2017 because "at a minimum, numerous complex systems changes would need to be made to allow an off-campus provider-based department to bill and be paid as another provider or supplier type." However, CMS currently pays hospitals, through the hospital bill, at the Medicare physician fee schedule (PFS) rate for a wide variety of services and situations, including screening mammography, physical therapy and other types of therapy, and certain preventive services. It also reimburses hospitals via the Critical Access Hospital Optional Payment Method (Method II) at PFS rates. While it may not be simple, CMS clearly has a mechanism at its disposal that it could use to pay hospitals directly for nonexcepted services under the PFS. The agency has a responsibility to work to be able to use this, or another, mechanism to provide reasonable payment to hospitals. It cannot implement its site-neutral policies until it addresses this unfairness.

Indeed, CMS has a long history of delaying the implementation date of new payment systems, even those with deadlines defined in law, when it was unable to implement them in a timely and responsible manner. For instance, CMS delayed the implementation of the:

- OPPS for 18 months, from Jan. 1, 1999 to July 1, 2000;
- ambulance fee schedule for 27 months, from Jan. 1, 2000 to April 1, 2002; and
- new market-based payment system for the clinical laboratory fee schedule for 12 months, from Jan. 1, 2017 to Jan. 1, 2018.

A delay also would provide CMS with the time it needs to operationalize other policies necessary to properly implement these site-neutral regulations. For example, in the proposed rule, CMS asked whether it should require hospitals to self-report information such as the identification of all individual excepted off-campus HOPDs, the date that each began billing under the OPPS and the clinical families of services that were provided prior to Nov. 2, 2015 (BiBA's date of enactment). If CMS moves forward with requiring an additional data collection, the two months between the release of the final rule (expected around Nov. 1) and the proposed implementation date of Jan. 1, 2017 would not provide sufficient time for either the agency to develop and test a system to gather this information from hospitals, or for hospitals to accurately and reliably report this data.

Additional Considerations for 2018. As CMS considers how to establish a more reasonable and workable payment policy for 2018, we urge the agency to further examine its other proposals related to site-neutrality, as outlined below. We are concerned that, as written, the rule would freeze the progress of off-campus clinical care in its tracks. We fear that CMS's rigid proposals

would negatively impact access to care for beneficiaries, particularly much-needed services for vulnerable populations in the nation's most underserved communities. For example, the agency's proposal to limit flexibility in relocation and expansion, in combination with its proposal to withhold hospital payments altogether, would mean that hospitals and health systems that have planned to provide or expand much-needed hospital-level outpatient care in urban and rural communities with limited access to care would not be able to do so. [Insert a short description of your hospital's plans to provide or expand HOPD services in communities with limited access to care.]

Relocation and Rebuilding. We are particularly troubled by CMS's unreasonable and inflexible proposal to discontinue current reimbursement under the OPPS for excepted HOPDs that need to relocate or rebuild. There are many necessary and valid reasons that excepted HOPDs would need to relocate – doing so should not cause them to lose payment. The impact on patients, including the loss of access to needed care, would be drastic in our community. CMS should allow for relocation and rebuilding of excepted HOPDs without triggering payment cuts.

Expansion of Services. CMS proposes that, if an excepted HOPD expands the types of services it provides on or after Nov. 2, 2015, those services be paid at the site-neutral rate. This is extremely problematic. Off-campus HOPDs must be able to expand the items and services that they offer in order to meet changes in clinical practice and the changing needs of their communities without losing their ability to be reimbursed under the OPPS. Given the rapid pace of technological advances in medicine, the treatments and services offered by HOPDs today will inevitably evolve into newer, innovative and more effective care in the future. CMS policy must not hamper access to innovative technologies and services. There are situations where new providers with differing skills would enhance a HOPDs offering of services. Nothing in BiBA requires that CMS treat expanded services in an excepted HOPD in this way. In fact, the plain language does not address relocation or expansion at all. CMS must ensure that patients continue to have access to the services they need at the facilities where they seek treatment. We strongly urge CMS to protect our hospital's ability to offer an expanded range of services without experiencing a loss of reimbursement.

Change of Ownership. We are concerned that CMS's proposal would not permit an excepted off-campus HOPD to retain its excepted status if it is individually acquired by another hospital. Often, hospitals in financial difficulty that plan to close their inpatient hospital beds will offer to transfer their HOPDs to better-performing hospitals in order to ensure that critical hospital-based outpatient services are still accessible to patients in the community. Such acquisitions would not be financially feasible if the HOPD were to lose its payment. We urge CMS to allow individual HOPDs to be transferred from one hospital to another and maintain their excepted status.

Impact on Provider Enrollment and 340B due to Section 603 of the Bipartisan Budget Act of 2015. The proposed regulations would implement new "site neutrality" requirements that will change the way certain off-campus hospital outpatient departments will be paid. The proposed regulations do not specifically discuss the eligibility of these off-campus hospital departments for the 340B Program. However, CMS specifically states that the off-campus outpatient departments would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of regulations governing its provider-based status. Under current HRSA guidance, an off-campus location of a hospital is eligible to participate in the 340B Program if the hospital is a covered entity and the off-campus location is a reimbursable cost center on the hospital's Medicare cost report and is registered with HRSA as a "child site." In order to be a reimbursable cost center, Medicare's provider-based requirements must be met.

CMS should provide additional comment on if providers can enroll off-campus hospital outpatient departments as a provider-based department even though it will be paid the non-facility rate as stated in the proposed rule. If a new off-campus hospital outpatient department meets all CMS requirements for provider-based status, can it be reported as a reimbursable cost center on the cost report for 340B reporting requirement? The proposed regulations have an impact on 340B drug program and we request CMS to confirm that new off-campus departments impacted by the proposed regulation can still be reported as reimbursable cost centers in order to meet the 340B HRSA requirements.

Additional clarification is needed for hospitals that move provider based offsite clinics after November 2015 as to whether they can still be a provider based department of the hospital but will only be paid on the Physician Fee Schedule. Please provide additional clarification on whether this rule impacts Medicaid Provider Based billing practices or if this will be up to each individual states Medicaid program on how this will be billed and paid.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services. We request that the use of an Appropriate Use Criteria tool for Advanced Diagnostic Imaging services not be required in the Emergency Department and hospital inpatient settings. Imaging services provided to patients in a hospital Emergency Department should be exempted from any requirement using an Appropriate Use Criteria tool for physician decision making. The immediacy of patient needs in an Emergency Department should preclude any delay in obtaining the needed imaging that could occur if an additional step is required to use an Appropriate Use Criteria tool. Also, physician medical judgement appropriate to patients in critical life threatening situations should be the principal driver of imaging services, rather than the use of an Appropriate Use Criteria tool. Unnecessary and unintended delays could occur for Emergency Department patients and for inpatients.

Physical Therapy, Occupational Therapy and Speech Language Therapy Billing. We request that CMS explicitly state in the Final Rule that physical therapy, occupational therapy and speech language therapy services which are currently paid on the Medicare Physician Fee Schedule may continue to be billed on the institutional claim (UB/837I) by hospital outpatient off-campus sites whether or not the site is considered grandfathered as a hospital outpatient based department under Section 603 of the Bipartisan Budget Act of 2015.

Physical Therapy, Occupational Therapy and Speech Language Therapy at Off-Campus sites. We also request that CMS explicitly state in the Final Rule that physical therapy, occupational therapy and speech language therapy services which are currently paid on the Medicare Physician Fee Schedule may be added as new services to grandfathered hospital outpatient department off-campus sites without limitation under Section 603 of the Bipartisan Budget Act of 2015. We also seek clarification that these new services may be billed on the institutional claim (UB/837I).

Billing system issues. The Proposed OPPS rule poses considerable obstacles to hospital billing systems and imposes an undue administrative burden for hospitals that would need to split some new clinical services between institutional claims (UB/837I) and professional claims (1500/ 837P) for Medicare without adequate lead time. CMS should carefully consider the amount of energy, effort and delayed payments involved for many hospitals who would not be ready to meet a 1/1/2017 deadline. CMS should also consider the impact on downstream secondary payers including the multiple state Medicaid programs that may not be 'suddenly' ready to accept professional claims (1500/ 837P) for services co-mingled with institutional claims (UB/837I) from a hospital outpatient off-campus department. Although CMS may have been contemplating this scenario for some time that is not true for the hospital community at large.

CMS should allow nonexcepted off-campus sites to continue to bill and be paid as hospital outpatient departments until 1/1/2018. This would allow time for numerous complex system changes to be made in order to accommodate these new instructions. Without adequate time for implementation, CMS could unintentionally cause shortages in the provision of patient care if they implement these site-neutral policies before making sure that hospitals are fairly and equitably paid for their off-site outpatient services.

At present, the CMS proposed rule does not contain a mechanism to directly reimburse nonexcepted hospital outpatient sites or nonexcepted services for imaging, chemotherapy, surgical and many other reasonable and necessary services we provide to Medicare beneficiaries. Instead, billing for these services would require the use of a physician's CMS-1500 claim to receive Physician Fee Schedule payment amounts and possibly involve new arrangements with non-employed physicians within a short and unexpected time frame. This could result in a possible lack of financial viability due to the receipt of considerably less revenue.

In conclusion, MHA, along with the American Hospital Association, urges CMS to delay the implementation of the site-neutral policies in the proposed rule by at least one year. This delay would provide the time necessary for CMS to develop a fair and flexible payment policy under

which hospitals would be able to receive direct payment for the their nonexcepted HOPDs and for nonexcepted items and services that they furnish in excepted HOPDs.

As always, we appreciate the opportunity to comment on CMS's proposed rules. If you have any questions, please feel free to contact me at (651) 659-1415 or jschindler@mnhospitals.org.

Sincerely,

Joseph A. Schindler
Vice President, Finance