Minnesota Hospital Association

2550 University Ave. W., Suite 350-S
St. Paul, MN 55114-1900
phone: (651) 641-1121; fax: (651) 659-1477
toll-free: (800) 462-5393; www.mnhospitals.org

September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Submitted electronically through www.regulations.gov.

Re: CMS–1678–P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (Vol. 82, No. 138), July 20, 2017.

Dear Ms. Verma:

On behalf of our 142 member hospitals and health systems, the Minnesota Hospital Association (MHA) offers the following comments and suggestions regarding the Centers for Medicare & Medicaid Services' (CMS) proposed rule for 2018 Medicaid Program; State Disproportionate Share Hospital Allotment Reductions (CMS-2394-P).

While we support many of the detailed comments submitted by the American Hospital Association, we are specifically responding in the following areas:

- Supervision of Hospital Outpatient Therapeutic Services
- 340B Drug Pricing
- Rural Adjustment
- Changes to the Inpatient Only List
- Request for Information on Flexibilities and Efficiencies

Supervision of Hospital Outpatient Therapeutic Services: In the CY 2009 and CY 2010 OPPS/ASC proposed rule and final rule with comment period, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, CAHs, and in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this proposed rule, CMS is proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and CY 2019.

MHA supports CMS's proposal to reinstate a moratorium on enforcement of its burdensome direct supervision requirement for outpatient therapeutic services provided in CAHs and small and rural hospitals. However, we continue to urge the agency to make the enforcement moratorium permanent and continuous

340B Drug Pricing: CMS is proposing changes to the current Medicare Part B drug payment methodology for 340B hospitals that it believes would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to share in some of the savings realized by hospitals participating in the 340B program. For CY 2018, CMS is proposing to exercise the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. In addition, in this proposed rule, CMS states its intent to establish a modifier to identify whether a drug billed under the OPPS was purchased under the 340B Drug Discount Program.

MHA strongly opposes CMS's proposal to reduce Medicare Part B payments for drugs acquired through the 340B Drug Pricing Program. We urge the agency to withdraw its proposal for the following reasons:

- CMS lacks the statutory authority to impose a Medicare Part B payment rate for 340B drugs that results in such a dramatic payment reduction that it effectively eliminates the benefits of the 340B program.
- Medicare payment cuts of this magnitude would greatly undermine 340B hospitals' ability to continue programs designed to improve access to services – which is the very goal of the 340B program that Congress intended.
- CMS's proposal would not directly benefit Medicare beneficiaries as it claims. In fact, seniors may end up paying more in co-payments under the proposal.
- Rather than addressing the real issue of the skyrocketing cost of pharmaceuticals, this proposal punitively targets 340B hospitals serving vulnerable patients, including those in rural areas.

CMS lacks the statutory authority to impose a Medicare Part B payment rate for 340B drugs that results in such a dramatic payment reduction and effectively eliminates the benefits of the 340B program. The agency's contention that it has specific statutory authority under subclause (II) of section 1395l(t)(14)(A)(iii) to reset the payment rate from ASP plus 6 percent to ASP minus 22.5 percent is contradicted by the plain and ordinary meaning of the text. It does not convey, as CMS asserts, the power to adopt a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would, according to the agency's own estimates, result in a reduction in payment to 340B hospitals of at least $900 million. Moreover, the overall structure of the statutory section that contains the precise provision that CMS purports to rely on for this proposal reinforces the limited and circumscribed authority for the agency to set the payment rate. CMS's proposal is not the slight alteration to the payment rate permitted under the statute. Indeed, according to estimates by the American

Hospital Association (AHA), CMS's proposal would reduce drug payments to 340B hospitals by $1.65 billion. It would effectively eviscerate the 340B program.

CMS's Proposed Cuts Would Undermine the Congressionally-mandated Mission of the 340B Program. CMS states that one goal of its proposal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." However, in reality, the proposal would do great harm to these hospitals that serve our most vulnerable citizens, undermining the purpose of the 340B program established by Congress. Specifically, it would undercut the 340B program's value as a tool for lowering drug prices and disrupt access to care for those in greatest need, including low-income Medicare beneficiaries.

Congress created the 340B program to permit hospitals that care for a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

As noted, many 340B hospitals are the lifelines of their community, and the discounts they receive through the 340B program play an important role in allowing these organizations to care for patients. However, these facilities are financially vulnerable. In 2015, one out of every four 340B hospitals had a negative operating margin. While hospitals overall had negative Medicare margins, 340B hospital margins are even worse. Specifically, 340B hospitals paid under OPPS had total and outpatient Medicare margins of negative 18.4 percent and negative 15.4 percent, respectively.

CMS's proposed cuts would make these hospitals' financial situations even more precarious, thus putting at great risk the programs they have developed to expand access to care for their vulnerable patient populations.

Most Medicare Beneficiaries Would Not Directly Benefit from CMS's Proposal. Part of CMS's rationale for proposing a reduction in payment for Part B drugs acquired under the 340B program is that the agency believes the proposal will reduce Medicare beneficiaries' drug copayments when seeking care from 340B hospitals. However, this is not accurate. The majority of Medicare beneficiaries coming to 340B hospitals do not pay their own copayments. According to a Medicare Payment Advisory Commission analysis, 86 percent of all Medicare beneficiaries have supplemental coverage that covers their copayments, of which 30 percent have their copayments paid for by a public program, such as Medicaid, or by their Medigap plan.[2] Thus, CMS's 340B payment reduction proposal would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included, as it so claims.

Concerns regarding CMS's Proposed Modifier for Non-340B Drugs. In order to identify which drugs are 340B and which are non-340B, CMS would require hospitals to report a modifier on the Medicare claim that would be reported with separately payable drugs that were

[1] https://www.hrsa.gov/opa/index.html
[2] MedPAC, June 2016 Databook, Section 3, p 27.

not acquired under the 340B program. Implementing CMS's proposed modifier would be administratively burdensome, costly to operationalize, and, for some hospitals, nearly impossible to implement. It also is at odds with the agency's commitment and active efforts to reduce regulatory burden for providers.

For example, CMS's approach is the exact opposite of how a number of state Medicaid agencies administer their Medicaid rebate programs to prevent duplicate discounts on 340B drugs. To accurately collect rebates, some state Medicaid agencies identify 340B drugs with a modifier or their National Drug Code (NDC) code so that if the modifier or NDC code is not on the claim, the drug is eligible for a Medicaid rebate. CMS's proposal is the exact opposite, and it will add confusion and complexity to an already complicated system.

In addition, we have significant concerns about whether hospitals can possibly implement CMS's proposed modifier accurately. That is, they would have to put the modifier onto the claim at the time service is rendered, or go back and retroactively apply it, thus delaying the submission of the claim. In particular, this would be difficult in mixed-use areas, such as emergency departments, catheterization laboratories and pharmacies, where both 340B eligible patients and non-340B patients are served.

In conclusion, we believe that CMS's proposed reduction in Medicare Part B payments for 340B drugs will put significant financial pressure on our safety net hospital organization, negatively impacting their ability to provide high-quality care to our Medicare beneficiaries and communities at large. **We urge CMS to abandon the 340B drug payment proposal and redirect its efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs.**

Rural Adjustment: CMS is proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

MHA supports this extension of the 7.1 percent adjustment to OPPS payments to certain SCHs and EACHs.

Changes to the Inpatient Only List: In CY 2017 OPPS/ASC rulemaking, CMS solicited comment from the public on whether total knee arthroplasty should be removed from the inpatient only list. Several commenters to the CY 2017 OPPS/ASC proposed rule were supportive of the removal. In addition, the Advisory Panel on Hospital Outpatient Payment recommended at its Summer 2016 meeting that this procedure be removed from the inpatient only list. After evaluating the procedure, for CY 2018, we are proposing to remove total knee arthroplasty from the inpatient-only list. In addition, CMS is soliciting comment on whether partial and total hip should also be removed from the inpatient only list and added to the ASC Covered Surgical Procedures List.

MHA disagrees with the CMS proposal to remove Total Knee Arthroplasty and Partial and Total Hip Arthroplasty procedures from the Inpatient Only List. We believe that keeping these procedures on the Inpatient Only List will support our shared goals of quality patient care and patient safety. The clinical risk factors and characteristics of the Medicare population justify continuing to require these invasive procedures to be performed on an inpatient basis for the Medicare patient population. Medicare should continue to require a hospital admission for these procedures and should assure adequate payment for them on an inpatient basis.

While we recognize certain instances in younger and healthier populations where uncomplicated surgeries might slowly migrate to an outpatient setting, we oppose the wholesale removal of this protection for Medicare patients who may require extended recovery time and are likely to have complicating factors.

Comprehensive APCs: For CY 2018, CMS is not proposing to create any new C-APCs or any extensive changes to the already established methodology used for C-APCs. There will be a total number of 62 C-APCs as of January 1, 2018. CMS notes that for CY 2018, for the C-APC for Stereotactic Radio Surgery (SRS), specifically, C-APC 5627 (Level 7 Radiation Therapy), we are proposing to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment. In addition, the data collection period for SRS claims with modifier "CP" is set to conclude on December 31, 2017. Accordingly, for CY 2018, CMS is deleting this modifier and discontinuing its required use.

MHA supports maintaining the stability of C-APCs for FY2018.

Request for Information on Flexibilities and Efficiencies

We are also providing recommendations for flexibilities and efficiencies in the following areas.

- Allowing Nurse Practitioners and Physician Assistants to Orders for Medical Nutrition Therapy
- Diabetes Self-Management Training and Medical Nutrition Therapy Coverage
- Calendar Year Orders for Medical Nutrition Therapy
- Medicare Secondary Payer Questionnaire for Ambulance Transports
- Improve Access and Payment for Telemedicine

Allowing Nurse Practitioners and Physician Assistants to Order Medical Nutrition Therapy From a practical standpoint, it is inconvenient, inconsistent and confusing for care teams that CMS does not currently allow Nurse Practitioners and Physician Assistants to write orders for Medical Nutrition Therapy. They are currently already allowed to write orders for Diabetes Self-Management services, and for clinical efficiency we ask that CMS make a change for CY 2018 to allow Nurse Practitioners and Physician Assistants to also write orders for Medical Nutrition Therapy. Requiring a separate order from a physician is unnecessary and merely adds time delays and costs to the provision of care.

Diabetes Self-Management Training and Medical Nutrition Therapy Coverage
The current regulation that does not allow patients to receive both DSMT and MNT on the same day creates unnecessary transportation burdens for patients and unnecessary scheduling burdens for providers. Allowing patients the flexibility to receive both DSMT and MNT services on the same day will promote the efficient, cost effective and patient-centered delivery of health care services. Having both services on the same day could reduce no-shows for appointments, save patient transportation costs and result in timelier provision of care.

Calendar Year Orders from Medical Nutrition Therapy
MHA requests that CMS allow orders for Medical Nutrition Therapy to be valid for a continuous period of time, not just the calendar year in which the order was written. Doing so makes sense, removes an unnecessary administrative burden and prevents a 'time crunch' at the end of the year for patients and providers alike. The current limitation is an unnecessary administrative burden.

Medicare Secondary Payor Questionnaire for Ambulance Transports
Hospitals are required to complete a Medicare Secondary Payor Questionnaire (MSPQ) for every registration created for their local emergency medical services (EMS). Because a significant percentage of patients that are treated and transported by a hospital's EMS are brought to facilities, completion of the MSPQ requires a phone call to every one of those patients, which delays an otherwise simple process, and holds up claim submission. We recommend that EMS services be excluded from the MSPQ process, as the medics in the field are focused on patient treatment, rather than clerical tasks.

The entire MSPQ process and the lengthy series of questions that we are required to ask Medicare patients at each visit is repetitive at best. This leads to patient dissatisfaction, and contributes to inefficient registration and scheduling processes. Answers to some of the questions on the MSPQ may already be recorded for any given patient in the Medicare Common Working File. We suggest the creation of an abbreviated version of the MSPQ that focuses on Third Party Liability situations.

Improve Access and Payment for Telemedicine Services for Medicare Beneficiaries
We offer our suggestions on telemedicine to improve the delivery of care for Medicare patients.

1. Remove the site of service limitation. Today Medicare coverage requires the patient to be at a limited set of healthcare facilities such as a clinic or hospital. This limitation is obsolete. Hospitals can better serve patients by offering care via telemedicine to the home, homeless shelter, or anywhere an appropriate connection can be established.
    - The Minnesota Medicaid program authorizes several more originating site types, including group homes, assisted living facilities and patients' homes when a licensed or certified health care provider can help with the delivery of telemedicine services.

2. Remove the geographic restriction. Today Medicare coverage requires that the patient is in a rural health professional shortage area. There are many instances when patients in urban locations could be better and more cost effectively cared for with telemedicine. It could be an important tool to reduce readmissions and improve access to services such as mental health.
    - Urban and rural patients need telemedicine because of homebound status, mobility limitations, transportation issues, clinic hours that conflict with inflexible work schedules, or other reasons that prevent them from coming to a hospital or clinic. These obstacles, that all too often prevent patients from arriving for in-person appointments, could be removed by cost effective telemedicine appointments.
    - Geographic restrictions of telehealth to rural areas are not imposed by our Minnesota state Medicaid program and we seek Medicare alignment with our state coverage.

3. Allow payment for telemedicine services for Medicare patients. Remove the restriction that limits telemedicine to only live interactive video. Utilizing 'store and forward (e.g. packaging of images and documentation)' methods for the review of medical documents in an asynchronous manner has been proven to be effective and efficient in specialties that are very visual in nature, such as dermatology.
    - Our Minnesota state Medicaid program allows payment for asynchronous (store and forward) services and we seek Medicare alignment with our state coverage.

4. MHA recommends that CMS include certain Physical Therapy (PT) and Occupational Therapy (OT) and Speech services in covered telemedicine. At certain hospitals with specialized services such as a Traumatic Brain Injury Center, hospitals provide high quality care to many patients that come from long distances for such therapy. Patients would greatly benefit from being able to receive their follow-up services for PT/OT/Speech through telehealth. This would promote access to the level of expertise and continuity of care with providers that produces optimum healthcare outcomes. It will also reduce transportation barriers for a patient population needing PT/OT/Speech services since they may have special mobility difficulties.

5. MHA recommends the addition of telemedicine coverage for Medical Nutrition Therapy and Diabetes Self- Management. Even urban hospital we have patients who come long distances or are homebound. This would be a patient-centered and time-saving option for our patients who could benefit from these services.

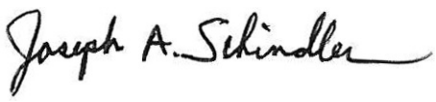
6. Consider allowing other types of non-physician practitioners to practice telemedicine and to have their services covered by Medicare. Not allowing or restricting Medicare coverage for Audiologists, Speech Language Pathologists, Registered Dieticians, Certified Diabetes Educators, Licensed Marriage and Family Therapists and Licensed Professional Clinical Counselors makes services more difficult to provide to Medicare beneficiaries, does not align with state Medicaid programs or other payers and prevents Medicare

beneficiary access to the full range of health care team services. We recommend that Medicare add these professionals and their services to the range of covered telemedicine services.

7. We also call special attention to the imperative need for more mental health services to be added to the list of those we can provide through telemedicine, in addition to day treatment, partial hospitalization, residential treatment services or face-to-face case management. We support the CMS plan to add telemedicine coverage for the psychotherapy crisis assessment codes 90839 and 90840. Patient access to mental health services is a vital priority as our providers seek to provide the best care possible to every patient we serve. This would begin to align Medicare requirements with those of other payers including our state Medicaid program, since other payers have either never had or no longer have these restrictions.

Thank you for your consideration of our comments. We also support the more detailed comments submitted by the American Hospital Association especially in the areas of the partial hospitalization program and quality measure changes. 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