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September 27, 2019

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

RE: CMS–1715–***Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations***

Dear Ms. Verma:

WHA was established in 1920 and is a voluntary membership association. We represent all of Wisconsin's hospitals and integrated health systems. Our members include small, mid and large-sized hospitals, including many Critical Access Hospitals and several large academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

Many of these entities employ or are closely affiliated with physicians and other providers. At the direction of our board of directors, to address the interests and concerns of our integrated health system members, WHA has developed a strategic physician agenda. Our comments on this proposed rule illustrate how these provisions impact physicians working in our members' health systems. On behalf of our members, WHA appreciates the opportunity to comment on the proposed rule.

Proposed Payment Reductions for Specific Code Groups in 2020

In the rule, CMS proposes significant reductions to the relative value units (RVUs) of certain CPT code groups – a move that could potentially limit patients' access to these vital services. For example, CMS's proposed valuations for the code set that describes long-term EEG monitoring with video recording – which is key to the care of patients with epilepsy – would result in a nearly 50% reduction in payment for these services. The RVUs that CMS proposes are even lower than the Relative Value Scale Update Committee (RUC)-recommended values, and, as such, do not reflect the level of time and expertise required to perform this specialized service. CMS similarly disagrees with the RUC-recommended values for the code set that describes myocardial PET scans and instead proposes RVUs that would result in a payment cut for these services. Decreases of this magnitude over a short time period will negatively impact physicians and hospitals that care for patients for whom these services are critical.

WHA opposes these drastic cuts and urges CMS to phase in substantial fluctuations in payment rates in order to promote predictability and reliability for providers, such as in this situation or when the RVUs for any CPT code set are drastically reduced in a given year.

Co-insurance for Colorectal Cancer Screening Tests

In general, beneficiaries are not required to pay Medicare Part B coinsurance for colorectal cancer screening tests. However, colonoscopies and sigmoidoscopies that begin as a screening service, but have a polyp or other growth removed as part of the procedure, are no longer considered "screening" tests, and carry coinsurance requirements for beneficiaries. We appreciate CMS's recognition of beneficiaries' and providers' concerns about the coinsurance when beneficiaries expected to receive a colorectal screening procedure, but instead received what Medicare considers to be a diagnostic procedure.

In this rule, CMS requests comment on whether it should introduce a notification requirement under which physicians or their staff would be required to inform beneficiaries before a colorectal cancer screening that they may incur a coinsurance payment if the physician discovers and removes polyps. We strongly recommend that CMS use its existing resources to inform beneficiaries of their possible coinsurance requirement, rather than providers. CMS is the appropriate entity to notify beneficiaries of their coinsurance requirements. Requiring physicians or their staff to provide this notification would introduce an additional, unnecessary regulatory burden, which could force them to divert important resources away from patient care. It also could create distrust among beneficiaries if providers begin their routine colorectal cancer screening with a warning about possible unexpected payment, rather than focusing on the care they are providing.

Evaluation and Management (E/M) Documentation Revisions and Payment Changes.

E/M Payment Changes

WHA strongly supports CMS's proposal to assign separate payments to all E/M visit levels for new and established patients. We appreciate CMS's response to our comments on the 2019 proposed rule expressing concern about consolidating five E/M reimbursement categories into two categories, which would have financially disadvantaged providers who see a more complex patient panel. WHA also generally supports the proposal to adopt the AMA RVS Update Committee's recommended valuations for all E/M codes and the prolonged services add-on codes for CY 2021 implementation. Providers that see patients at the higher-level codes for E/M visits will likely see the greatest increases, while providers that don't generally bill E/M office visits could see greater decreases. That being said, we urge CMS to closely monitor the impact of these recommended valuations on providers who do not perform E/M visits when it establishes the 2021 PFS conversion factor due to the uncertainty the changes may cause, given the necessity for the PFS to be budget-neutral.

WHA also supports the proposal to require providers to perform the history and exam elements of the current E/M codes only when medically necessary and clinically appropriate, and to instead use either the level of medical decision-making or the level of time personally spent by the reporting practitioner on the date of the visit when considering the code level selection.

E/M Documentation changes

WHA supports CMS's proposals to streamline E/M documentation. Reducing physician burnout is a top advocacy priority for WHA. Much of this burnout results from the heavy load of documentation within an EHR that is required for reimbursement, and whenever a requirement can be removed that does not support good patient care, that should be done. Last year's final PFS rule permitted physicians, residents and nurses to document a teaching clinician's presence during the time the teaching clinician participates in services involving the residents, rather than requiring the teaching clinician to document this information him or herself. WHA strongly supports CMS's proposal to extend these flexibilities to other practitioners by establishing the general principle that physicians, physician assistants, and advanced practice registered nurses who furnish and bill for their professional services would be permitted to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students and other members of the medical team.

Payment for Care Management Services

WHA appreciates CMS's recognition of the current low utilization of care management services and supports its proposal to make changes to care management codes, which will hopefully increase utilization of these codes. In the past several years, WHA has engaged in policy development and advocacy to increase care management within the Wisconsin Medicaid program and are pleased to see efforts to increase utilization of these services with the Medicare program. We support the following changes to care management within the Medicare program:

- Transitional Care Management: We support the increase in payment rates for TCM services, as well as the proposal to relieve some of the administrative burden in billing for these services by permitting concurrent billing with 14 HCPCS codes that that are currently paid separately under the PFS.
- Chronic Care Management: WHA supports the proposal to adopt new G codes for CCM which recognize the additional time that is frequently needed to perform non-complex CCM. We also support the adoption of two new G codes that would replace the current CPT code for complex CCM services, because they would not contain the substantial care plan revision requirement.

WHA also supports CMS' proposal to allow Remote Physiologic Monitoring (RPM) to be furnished under general supervision rather than direct supervision. These proposals will enable RPM tools and services to realize their full potential in chronic care management of Medicare beneficiaries.

Opioid Treatment Programs – Medicare Part B benefit

CMS is proposing to establish bundled payments for the treatment of Substance Use Disorders (SUDs), including Opioid Use Disorders (OUDs), outside of established treatment programs. Services involving management, care coordination, psychotherapy, and counseling activities would be covered under the bundled payments. Although CMS starts with the assumption that patients will need two individual psychotherapy sessions per month and four group psychotherapy sessions, the agency acknowledges that the number of sessions will vary among patients and fluctuate over time.

Creating a separate bundled payment for these services should incentivize providers to furnish counseling and care coordination for patients with SUD/OUD in the office setting and give these

patients more opportunities to seek help outside of a treatment program. CMS is proposing three new codes to capture these bundled services. We support the proposal to add these three new codes to Medicare's telehealth list. However, CMS's position that a practitioner who is providing psychotherapy services to address a mental health disorder would not be able to provide these services to address SUD/OUD in the same month. Restricting patients to a limited number of hours of psychotherapy under a bundled payment treatment program may prevent them from receiving sufficient psychotherapy services needed to address their underlying issues and ultimately hinder their SUD/OUD treatment. We ask CMS to allow providers to furnish additional psychotherapy services to address co-occurring mental health issues of patients receiving treatment for SUD/OUD.

Finally, WHA is concerned about the proposal to price the Part B injectable and implantable drugs used int eh bundle using the average sales price without the standards 6% add-on. WHA is opposed to not including the 6% add-on. CMS is obligated to include a factor for overhead and to adequately justify any add-on less than the standards 6% with data, and that is not done in this proposed rule.

Stark Law Advisory Opinions

CMS proposes some modifications to the Stark Law advisory opinion process. We are disappointed that CMS declines to expand the advisory opinion process to requests that involve hypothetical situations and general questions of interpretation. However, we favor the proposed relaxing of the current rule that prohibits CMS from accepting a request for or issuing an advisory opinion if the agency is aware of pending or past investigations or proceedings involving a course of action that is "substantially the same" as that described in the advisory opinion request. That language is relaxed to indicate that CMS "may elect not to" issue an advisory opinion in that situation, if certain criteria met.

As mentioned in our 2018 letter providing feedback to CMS on the Stark Law, we support Congressional attention to the area of the statute that imposes strict liability. We believe CMS should work with stakeholders to develop statutory changes that would permit CMS to consider whether there is an intent to violate the statute when investigating violations. At present, the threat of unintentional violations is a major risk that many organizations are not willing to take. If we are going to see a wider movement toward value-based alternative payment methodologies, embraced by both
large integrated and small independent health systems, then this area of the statute must be reformed.

In the meantime, CMS should do what is within its authority to prioritize intentional versus unintentional, technical violations. Transparency in relationships as well as the potential benefit of referrals and their impact on patients should be encouraged so that providers acting in good faith with good intentions are not unduly penalized.

Payment for Therapy Services

The rule proposes payment changes for therapy services when furnished concurrently, or separately within the same visit, by Physical Therapists/PT assistants and Occupational Therapists/OT assistants. If 10% or more of services in a therapy visit are furnished by a PT or OT assistant, the visit must be coded with a modifier which indicates that. Once the modifiers attach, the visit would be paid at the 85% of the PT/OT reimbursement rate. The new coding requirements would take effect in the 2020 payment year. Payment cuts would be effective in the 2022 payment year.

WHA opposes CMS' proposed approach to assigning these modifiers when team-based care is delivered. Under Medicare policy, the physical therapist is responsible for the patient's plan of care, and the assistant

furnishes services under the direction and supervision of the therapist. When a therapist and assistant are jointly furnishing services to a patient at the same time, and the therapist is fully engaged in the service during that time. Further, there are instances when both the PT or OT and an assistant must work together to ensure patient safety. The service during that time period should be identified as a therapist's services and be allocated to the therapist. Only services furnished in whole or in part independently by the assistant should be attributed to the 10% de minimis standard for the assignment of the modifiers.

Quality Payment Program (MACRA) Changes

Merit-Based Incentive Payment System (MIPS) Proposed Changes

Quality measurement category: CMS proposes notable changes to two policies -- data completeness thresholds and performance benchmarks for certain measures.

- Data Completeness Thresholds. For the CY 2020 performance period, CMS proposes to increase the data completeness thresholds for four of the six MIPS data collection types from 60 to 70% of the clinician or group's patients that meet measure denominator criteria. Citing 2017 data showing that the average MIPS data completeness across clinicians and groups was 74% or better, CMS asserts that raising the threshold is appropriate at this time. WHA supports raising the data completeness threshold from 60 to 70 percent, given that the average data completeness score for clinicians in 2017 was 74%.

- Performance Benchmarks: CMS scores MIPS quality measures using deciles, assigning between one and 10 points to each measure. The deciles are set based on the performance of all providers nationally. However, CMS and stakeholders have identified some measures where the performance score for the top national decile is so high that it may inadvertently incentivize inappropriate treatment to achieve that decile.

CMS proposes that for measures whose historical top decile performance is greater than 90%, the agency would use "flat percentage benchmarks." That is, any performance rate at or above 90% would be considered in the top decile. WHA supports using flat performance benchmarks for those measures for which the top decile percentage is 90% or better, given that there are only two MIPS measures that would fit this description.

Cost/Resource Use Category: For the CY 2020 reporting period, CMS proposes modifications to the overall cost measures and would add 10 more episode-based cost measures. CMS proposes changes to two measures: Total Per Capita Costs (TPCC) and Medicare Spending Per Beneficiary (MSPB)

WHA appreciates CMS's responsiveness to stakeholder concerns regarding the TPCC and MSPB measures. The changes in the TPCC measures may lessen the chance that costs over which the clinician/group does not have any control will be attributed to them. These changes also lessen the chance that certain non-primary care specialists being held inappropriately responsible for the primary care costs of beneficiaries. Lastly, the changes in the risk adjustment approach will better account for differences in performance risk.

WHA also supports the proposed changes to the MSPB measure, responding to stakeholder concerns that the current measure results in the attribution of costs over which the clinician/group does not have any control, and makes certain non-primary care specialists inappropriately responsible for the primary care costs of beneficiaries.

Improvement Activity Category: CMS proposes to establish seven factors that it would consider in whether to remove particular improvement activities from its inventory, such as the activity is duplicative of another activity, there is an alternative activity with a stronger relationship to quality care of improvements in clinical practice, or the activity does not align with current guideline or practice. Second, for groups and virtual groups, CMS proposes to increase the requirement for how many clinicians within the group must participate in the activity. Rather than requiring that only one clinician from the group complete an activity, CMS would require that at least 50% of the group's NPIs perform the activity for the same continuous 90-day performance period.

WHA supports using the 7 factors outlined in the proposed rule to evaluate whether to remove an IA. WHA further supports a requirement that more than one clinician from a group must complete an IA activity, However, we are unsure that increasing the participation requirement to 50 percent is the correct level at this time is warranted. Perhaps a number between one clinician and 50% of clinicians is appropriate, but identifying the correct number needs further study.

Promoting Interoperability Category: CMS would remove the requirement to verify the opioid treatment agreements bonus measure after receiving significant feedback from stakeholders that the measure was burdensome and difficult to understand. CMS is also proposing to retain the Query of PDMP as a bonus measure for CY 2020 that is worth 5 points. CMS believes that additional time is needed to make the PDMP measure part of eligible clinician workflows. The measure would continue to be reported as a Yes/No attestation rather than a numerator/denominator measure.

CMS proposes to continue the rule that NPs, PAs, CRNAs, and CNSs and physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals can reweight their scoring from Promoting Interoperability by not reporting any measures. Data has shown that most of these eligible clinicians are not reporting the Promoting Interoperability measures. Consequently, CMS believes that it does not have enough data to make this category required for these clinician types at this time.

In WHA's comments on the 2019 PFS proposed rule, we opposed finalizing the "Verify Opioid Treatment Agreement" measure for MIPS PI performance category. We appreciate CMS's acknowledgement that this measure is burdensome and difficult to understand and support the proposed removal of this measure from the 2020 reporting period. WHA also supports CMS's proposal to permit advanced practice providers to reweight their scoring from PI by not reporting any measure.

MIPS Category Weights: CMS is proposing to re-weight the MIPS categories for the 2020 performance year by increasing the cost category weight from 15% to 20% and decreasing the weight of the quality category from 45% to 40%.

WHA does not support CMS's re-weighting proposal. CMS should maintain the current weight of the Cost category for 2020.

In our comments on the 2018 updates to the QPP, we supported keeping the scoring of this category at 0% for the 2020 payment year because we did not believe that CMS had the correct mix of cost measures, nor did clinicians have experience with the measures. CMS finalized their proposal to score the cost category at 10 % for CY 2020 and 15% for CY 2021. We urge maintaining this percentage until clinicians have experience with a correct mix of cost measures, and until more measures are endorsed by the National Quality Forum.

MIPS Value Pathways (MVPs) For CY 2021, CMS proposes to begin implementing MVPs that it believes would align and reduce reporting requirements across the four MIPS performance categories. The rule does not propose any specific MVPs, but proposes a general framework, provides some examples and includes a request for information on how CMS could structure in future rulemaking.

CMS envisions that MVPs would eventually replace the current structure of the MIPS program, and that clinicians/groups would choose – or be assigned to – a particular MVP. The theory is that this would reduce reporting burden for those participating in MVPs by using a smaller number of quality and cost measures, and is exploring mechanisms of enhancing its mechanisms of sharing data with providers. Bundling quality and cost measures and improvement activities that are highly correlated in addition to the measures from the Promoting Interoperability performance category will strengthen clinical improvement and streamline reporting. As an initial step, CMS is proposing to require that, beginning with the 2020 call for measures process, quality measure stewards must link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible.

WHA supports the concept of re-organizing the MIPS reporting requirements for each category, but the MVP concept is simply not conceptually ready for implementation in CY 2021.This movement towards more standardized measure sets may improve results' accuracy and comparability. Focusing MIPS clinicians on smaller sets of specialty and disease-focused measures will reduce the ability to "cherry pick" measures that may skew MIPS results that impact bonuses, penalties, and usefulness for comparison. However, such rapid implementation may result in proposing measures that have not been tested and verified and may defeat the purpose of creating MVPs.

The linkage of quality measures with cost and improvement activity measures could make the overall QPP more coherent. However, the requirement in the 2020 call for measures process that measure stewards link the existing measures to cost and improvement activity measures appears to be an unfunded mandate and cannot be achieved with currently existing resources.

Advanced Alternative Payment Model (APM) Changes

While CMS mostly maintains the Advanced APM criteria for the coming payment year, it proposes to expand the definition of medical homes to include those which are operated by another payer that is formally collaborating in a CMS multi-payer model through a collaborative agreement. WHA supports this proposal and CMS's recognition that other payers apart from Medicare are working on medical home models.

Thank you for the opportunity to comment on this proposed rule. If you have questions, please contact Laura Rose, Vice President of Policy Development, at lrose@wha.org.

Sincerely,

/s/

Eric Borgerding
President and CEO