Atrium Health (GA, NC)

Avera Health (IA, MN, NE, ND, SD)

Community Hospital Anderson (IN)

Erlanger Health System (TN)

Franciscan Missionaries of Our Lady Health System (LA)

Hartford Healthcare (CT)

Oregon Health & Science University (OR)

SSM Health (IL, MO, OK, WI)

University of Florida Health-Central Florida (FL)

University of Pittsburgh Medical Center (PA, NY)

October 3, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: [CMS-1734-P] RIN 0938-AU10. Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Ms. Verma,

The Provider Roundtable (PRT) submits the following comments on the Physician Fee Schedule, as published in the *Federal Register*.

The Provider Roundtable (PRT) includes 15 representatives from various health systems, serving patients in 19 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services by CMS, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual policymaking process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Attachment A.**

Please feel free to contact me at 765-298-2110 or via email at: *trinker@ecommunity.com*.

Sincerely,

Terri Rinker, MT (ASCP), MHA
PRT Chair and
Revenue Cycle Director
Community Hospital Anderson
Anderson, IN

D. Telehealth and Other Services Involving Communications Technology

The PRT wishes, first and foremost, to acknowledge the diligent and timely work performed by CMS to respond to the global pandemic and public health emergency (PHE). The agency's response ensured that critical patient care services could be maintained during the PHE. Expanded access to telehealth services prevented patients from serious and potentially dangerous lack of access to care and ensured safe delivery of care for both patients and providers. On behalf of the entire provider community, we thank you for your hard work during the pandemic.

One of the most significant and positive disruptions stemming from the COVID-19 PHE is the rapid expansion of telehealth, and telehealth's clear acceptance as a safe, effective, and efficient way to provide clinical services. As a result of the waivers allowing for continued stability of payment during the PHE, patients have been able to participate in, and benefit from, accessing services via two-way telecommunications. In fact, many patients and clinicians are likely to resist returning to pre-COVID norms, with respect to telehealth services.

In the Proposed Rule, CMS describes three categories of telehealth services:
1. Telehealth services that were in existence prior to the PHE.
2. Telehealth services that were added as a result of the PHE and that will cease payment after the end of the PHE.
3. Telehealth services that do not currently have sufficient evidence to be a covered telehealth service after the PHE ends.

We understand that CMS is bound by the current regulations governing telehealth services. Nonetheless, the PRT encourages CMS to think creatively about how the agency can continue to use and advance the telehealth modality in the future, to the extent that its existing authority enables it to do so.

We recommend that the agency consider utilizing concepts similar to the provision of Coverage with Evidence Development (CED). CMS could allow coverage of telehealth services in exchange for documenting quality improvements and program success via a national registry. With additional evidence gained from registry entries, some services may present themselves as being clinically appropriate (if not clinically superior) when provided via telehealth.

Several likely candidates are being demonstrated during the PHE, and many physician services were successfully, safely, efficiently, and effectively provided via telehealth. The decreased exposure for physicians, practitioners, staff, and beneficiaries provided many levels of safety during the PHE. These include the ability to conduct office visits and emergency visits; contacting the primary provider rather than presenting at an ED for a service that is not a "true" emergency; supervising services via a remote presence; providing therapy services— just to name a few. The result is patient care that is safe, efficient, and comforting to all parties during the PHE. In fact, some preliminary responses from practitioners indicate that many services (e.g., physical therapy, follow-up office visits) were more consistently attended by patients than when a face-to-face encounter was required.

For some clinical specialties social distancing will remain an important OSHA safety protocol, where telehealth services could provide an enormous benefit to patients, physicians, employers, and other patients. These include infectious diseases, for example. The opportunity to reduce exposures has wide clinical utility that can improve safety and quality of care, reduce admissions

and readmissions, and lower costs—all of which are among CMS' documented goals. The PRT believes that supporting telehealth expansion "checks many boxes" for CMS.

Physicians who are in hospitals may need to maintain social distancing while providing important care to hospital inpatients via the use of technology. The PRT recommends that CMS consider developing a new place of service to designate virtual services provided to inpatients (i.e., the physician is in the hospital and the patient is an inpatient, but technology is used to render the services). A new place of service would offer clinicians the ability to report virtual services in lieu of in-person that are not telehealth services that require the physician to be at a distant location, but that are provided to inpatients in infectious isolation.

The use of a new place of service code for virtual services in lieu of in-person services provided to inpatients will allow CMS to gather quality data and expand access for specialized clinicians. This place of service could be valued similarly to the traditional inpatient place of service (21); however, distinguishing the virtual modality from traditional inpatient care will allow CMS to obtain important information about the effectiveness of the telehealth modality.

- **The PRT recommends that CMS expand telehealth services to the full extent of its statutory authority.**

- **The PRT recommends that CMS consider a Coverage with Evidence Development registry process to allow data to be gathered to support other services that meet the criteria for telehealth coverage.**

- **The PRT recommends that CMS develop a new place of service to designate telehealth services provided to inpatients.**

<u>MPFS Remote Monitoring Services</u>

CMS requests comments on how to distinguish the technical component of the remote monitoring portion of the service from the diagnosis-related group (DRG) payment already being provided to the hospital.

CMS also requested comments on how the agency could provide payment for monitoring and intervention services provided to Medicare beneficiaries in circumstances when the remote intensivist is monitoring multiple patients—some of whom may not be Medicare beneficiaries.

We note that physicians are accustomed to documenting services provided to individual patients. Electronic Medical Records (EMRs) are very successful in tracking services provided to each individual patient. CMS could use a process similar to the current process for reporting mileage for laboratory drawing services – the mileage for the individual patient is recorded and Medicare is billed for mileage only for Medicare beneficiaries. Similarly, the amount of time spent for each patient could be recorded and the physician would bill Medicare only for the time that was spent for the individual beneficiary. The physician would have the time documentation in the EMR entries to support the individual times, if CMS requests such validation. This process would ensure that no payments are made for patients who are not Medicare beneficiaries.

- **The PRT recommends that CMS institute a billing policy that the physician bill**

Medicare for the time spent for the individual beneficiary, using the information contained in the EMRs to support the time billed. This would allow CMS to confirm that payments are not provided for patients who are not Medicare beneficiaries.

CMS also seeks comments on how remote monitoring services intersect with both the critical care consult G-codes and the in-person critical care services. CMS' goal is to not have any overlap of services provided by clinical groups. Existing billing requirements for clinicians of the same taxonomy appear to protect the program from paying for overlapping activities, however. CMS may want to consider additional written instructions for providers to use when reporting these services.

- **The PRT believes that the existing taxonomy code and billing requirement systems for clinicians in the same clinical group will effectively manage these concerns.**

F. Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M and Promote Payment Stability during the COVID-19 Pandemic

Changes Related to Office Visits

The PRT fully supports CMS' adoption of the proposed changes related to office visits, which are designed to simplify documentation requirements and reduce excessive administrative burdens for providers regarding Evaluation & Management (E/M) services. This change will allow physicians and other eligible providers to spend more time with patients and less on paperwork.

The PRT appreciates CMS' efforts to streamline and simplify documentation required to support an office visit by proposing to:

1. Eliminate the history and physical exam component unless it is relative to the specific visit.
2. Modify the Medical Decision Management (MDM) criteria and move away from simply adding up tasks (such as number of diagnoses or management options, amount and or complexity of data reviewed, risk of complications and or morbidity or mortality).
3. Allow physicians and other practitioners to choose whether the visit code is based on MDM or total time and adopt the actual total time the reporting provider spent on the day of the visit, including face-to-face and non-face-to-face time.

- **The PRT supports CMS' proposals noted above, which will improve the quality of time that providers can spend with patients, and are likely to result in improved physician/practitioner relationships with their patients. We particularly applaud CMS for selecting the actual total time methodology for E/M visits rather than the RUC-recommend "Total Time."**

PFS Relativity Adjustor for Non-excepted Off-campus Provider-based Departments

While not a specific proposal in the MPFS rule, CMS previously finalized a policy that, when stakeholders believe there are changes warranting CMS' re-evaluation of the 60% PFS relativity adjustor, the issue(s) should be raised.

The PRT asks that CMS recalculate the adjustor based on the updates to the E/M service relative value changes finalized for CY 2021 and subsequent years. CMS maps hospital billing to E/M codes when calculating the PFS relativity adjustor and compares payment. Since MPFS payments would increase, the PRT assumes that the relativity adjustor would also increase. We believe that this is sufficient rationale for CMS to re-calculate the adjustor.

- **The PRT asks that CMS recalculate the adjustor based on the updates to the E/M service relative value changes finalized for CY 2021 and subsequent years.**

H. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services (FR 50252)

CMS solicited comments in both the CY 2020 Professional Fee Schedule Proposed Rule and the CY 2020 Home Health Proposed Rule regarding the appropriate form, manner, and frequency that a physician must use to provide notification of the treatment options available to patients for furnishing infusion therapy (home or otherwise) under Medicare Part B. Based upon review of the feedback provided, CMS is not going to create a mandatory form or implement additional requirements related to patient notification for infusion therapy options.

- **The PRT appreciates that CMS listened to providers' feedback and is not moving forward with any additional requirements related to patient notification of infusion therapy options.**

I. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTP)

In the CY 2020 PFS Final Rule, CMS established a list of services that may be furnished by opioid treatment programs (OTPs) under the new Medicare benefit; CMS also issued enrollment requirements for newly Medicare-eligible OTPs. For CY 2021, CMS proposes to add an additional service to the list of reimbursable services, offer new flexibility for enrollment, and clarify activities that may be reimbursed under a specific add-on code.

First, CMS proposes expand the definition of opioid use disorder (OUD) treatment services by adding naloxone dispensing to the list of eligible OUD treatment services that OTPs can furnish when it is medically necessary and within established frequency limits. CMS believes that this will increase access to care and eliminate the need for the beneficiary to see additional providers.

Second, CMS proposes to establish two new add-on codes to address instances when OTPs provide naloxone to Medicare beneficiaries. One code accounts for dispensing a take-home supply of nasal naloxone; the second accounts for a take-home supply of auto-injector naloxone. Third, CMS proposes a pricing methodology that is similar to that finalized for the drug component of the weekly bundle established in the CY 2020 PFS Final Rule. The two add-on codes would be priced as follows: HCPCS code GOTP1 for take-home supply of nasal naloxone: average sales price (ASP) plus zero percent add-on (ASP+0); and HCPCS code GOTP2 for take-home supply of auto-injector naloxone: wholesale acquisition cost (WAC) of the generic formulation plus zero percent.

- **The PRT supports all three CMS proposals.**

In addition to the proposed provisions, CMS seeks comments on how the agency might further refine the addition of naloxone dispensing to the Part B benefit. Specifically, CMS asks for comments on:

1. Whether CMS should create another add-on code for payment for injectable naloxone.
2. Whether the definition of OUD treatment services should be further expanded to include overdose education; and whether the weekly bundled payments for episodes of care should include payment for providing this education to the beneficiary and/or the beneficiary's family, or if CMS should establish a separate add-on payment to cover such overdose education.

The PRT agrees that CMS should create an add-on code and make separate reimbursement for the injection of naloxone. We also agree that treatment services should be expanded to include critical items such as overdose education for both beneficiaries and their family. We feel that an add-on code with separate payment is the optimal way to capture this critical service.

- **The PRT supports all of CMS' proposals, which will help identify and treat Medicare beneficiaries who have opioid use disorder.**

Including Screening for Substance Use Disorder in Physicals

Section 2002 of the SUPPORT Act requires the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions. The PRT agrees that this is a perfect fit for both the IPPE and the AWV, since both services focus on health promotion and risk assessment along with disease prevention. We agree that these are the perfect places for CMS to add these elements in order to fulfill the provisions of the SUPPORT Act.

- **The PRT supports this proposal.**

J. Proposal to Remove Selected National Coverage Determinations

The PRT understands that CMS proposes to sunset nine NCDs on the basis that they are not clinically pertinent and could impede innovation. We agree, in principle, that an NCD could be retired if CMS determines that it is completely outdated with respect to evidence-based medicine, and when current medical practice points to different therapeutic or diagnostic services from that in the NCD.

Nonetheless, we are *very* concerned about access barriers that are very likely to occur nationwide, and across MACs, with the result that coverage and patient care could be significantly impeded. We outline our concerns below.

First, NCDs that address current therapeutic and/or diagnostic services act as a foundation (or floor) for consistent access to care by all Medicare beneficiaries. Retiring NCDs and relegating coverage determinations to the MACs would jeopardize this foundation and result in variations in care across MACs.

Second, medicine is very different than it was when Medicare began in the 1960s. It is much less appropriate for state or regional entities to make determinations about patient care than it was 60 years ago. The advent of evidence-based medicine means that a central entity should determine what best-practice therapeutic and/or diagnostic services should be available throughout the system, such as via an NDC, rather than leaving this up to a local entity.

Third, MACs lack the experience and resources to stay up-to-date on rapidly evolving evidence-based practices. For each MAC to assume this responsibility, so that it can make a determination about a service previously covered by an NCD, would be an enormous duplication of effort. MAC's medical directors simply cannot be experts in all aspects of medicine. Having an NCD issued from CMS as a whole fosters specialization and efficiencies and saves resources.

Fourth, leaving discretion up the MACs will inevitably introduce confusion and inconsistency to coverage determinations. Historically, MACs have provided different coverage determinations for the same service. Providers experience this every day. It is highly likely that MACs will follow the same decision-making process that produces continued lack of uniformity. This lack of uniformity will be particularly problematic for facilities that serve patients and areas covered by more than one MAC. Many PRT hospital systems are governed by more than 1 MAC, based on feedback from 10 of our 15 members (see chart).

Provider	Number of Hospitals	Number of MACs
A	2	2
B	6	1
C	20	3
D	2	1
E	12	1
F	40	4
G	7	1
H	5	2
I	32	1 (2 jurisdictions)
J	36	4

It will be challenging to track and complicated to explain why patient care is sometimes covered but sometimes not. Some of our providers serve patients who travel to a different state (i.e., where they have a second residence) and receive a service covered by Medicare. The MAC in this second state has deemed the service to be covered; the MAC in the first state has deemed it to be non-covered. Beneficiaries who do not have multiple residences in multiple MAC jurisdictions do not have the luxury of residing where their needed services are covered; they are, thus, prevented from accessing services unless they have the monetary resources to pay for them outright.

Fifth, CMS' proposal to eliminate NCDs reduces guaranteed coverage for beneficiaries who participate in Medicare Advantage (MA) plans, since these plans are required to follow NCDs, but not LCDs. With enrollment in MA plans growing at a rapid rate, the PRT believes CMS' proposal will create new, and problematic, access to care issues for these beneficiaries.

- **The PRT opposes the proposal to eliminate specific NCDs and relegate coverage decisions to the MACs.**

Rather than implement this confusing and unnecessary policy, we recommend that CMS expand access to care and innovation by directing its MACs to examine the scientific evidence brought to them regarding aspects of care about which NCDs are silent; encourage MACs to grant meetings in a timely manner; and respond in a timely manner (i.e., within 60 days) to the request for coverage.

One suggestion is to designate the NCDs as the minimum floor or threshold for coverage of treatment, and explicitly clarify that MACs have discretion to cover therapeutic and diagnostic services above and beyond the NCD. The provider must prove that the circumstances meet the statutory definition of "medical necessity." If CMS implemented such a policy, we further recommend that any MAC coverage decision that exceeds an NCD be published in the Medicare coverage database, in a searchable manner that can be accessed by MACs and providers alike (PHI redacted, of course). This would demonstrate the specific circumstances when coverage was deemed medically necessary outside the minimum coverage and provide information to be used as a reference across all MACS. CMS would be able to rely upon this information to refresh/update the NCDs when and if the agency believes that to be necessary.

We think this approach balances the need for consistent and national beneficiary access with the need to keep access current with rapidly evolving evidence-based medicine.

Provider Roundtable: c/o Community Hospital Anderson, Anderson, IN
Attention: Terri Rinker, MT (ASCP), MHA, Revenue Cycle Director
1515 N. Madison Avenue, Anderson, IN 46011

Provider Roundtable

Attachment A: Provider Roundtable Members

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* *Non-voting past PRT member*

Updated July 2020

Provider Roundtable: c/o Community Hospital Anderson, Anderson, IN
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