AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS-5531-IFC; 85 Fed. Reg. 27550, May 8, 2020)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding additional policy and regulatory revisions in response to the COVID-19 Public Health Emergency (PHE) and delay of certain reporting requirements for the Skilled Nursing Facility Quality Reporting Program. The AMA greatly appreciates the flexibilities extended to our members to allow them to serve their patients during the Public Health Emergency[1] caused by the novel coronavirus disease 2019 (COVID-19). The AMA provided comments previously to the Interim Final Rule with Comments (IFC) where a number of the regulations discussed in the current IFC originally appeared.

We recognize that the pandemic requires greater cooperation throughout our health care system to reduce the infection and spread, and to treat those impacted by COVID-19. We are especially committed to policies that can provide access to marginalized and minoritized communities that have been disproportionately impacted by the COVID-19 pandemic. The following are our key points, with our detailed comments below:

- Physician-led teams which incorporate the skills and strengths of each team member deliver the most benefit to patients. Practicing within the scope of practice limits in a physician-led care team should be the standard, even during the COVID-19 PHE.
- CMS should monitor the costs and the quality of care resulting from its decision to allow non-physician practitioners to supervise diagnostic tests, as this expansion of non-physician practitioners' scope of practice has not been tested or proven for quality.

[1] On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a national Public Health Emergency (PHE) in responding to COVID-19. On April 21, 2020, Secretary Azar renewed the PHE, effective April 26, 2020.

- Although not required by regulation, COVID-19 test results should be shared with an individual's physician for the coordination services in light of comorbid conditions and other risk factors.
- Individuals in opioid treatment programs should be able to access therapy and counseling by telephone and periodic assessments by telehealth or telephone if appropriate or necessary.
- Medical education and physician teaching rules are appropriately adjusted to consider the temporary staffing adjustments due to the COVID-19 PHE while preserving graduate medical education payments.
- Delaying the 2021 Qualified Clinical Data Registry (QCDR) testing requirement is appropriate, given the difficulty for QCDRs to adhere to the timelines and requirements considering the COVID-19 PHE.
- Updates to remote patient monitoring are positive and should extend to coverage of home blood pressure monitoring as well.

I. Scope of Practice

Home Health

The Coronavirus Aid, Relief, and Economic Security (CARES) Act[2] authorizes nurse practitioners, clinical nurse specialists, and physician assistants, as those health care professionals who are defined in the Social Security Act, working in accordance with state law, to certify the need for home health services in Medicare and Medicaid and oversee patients' plans of care. CMS finalized these changes as permanent, effective for dates of service starting March 1, 2020, as the agency believes more patients may be considered homebound during the COVID-19 pandemic. State laws continue to apply and determine whether a non-physician practitioner may work independently, without a written collaborative agreement or supervision from a physician, or whether general or direct supervision by a physician or collaboration is required.

The AMA has long supported physician-led health care teams, with each member drawing on his or her specific strengths, working together, and sharing decisions and information for the benefit of the patient. We value the role of non-physician professionals functioning as part of a physician-led team; however, we do not support non-physician practitioners practicing independently to certify and oversee Medicare patients' home health care. While all health care professionals play a critical role in providing care to patients, their skillsets are not interchangeable with that of fully trained physicians.

There are other ways that CMS can reduce burden and expand access to home health services during the COVID-19 pandemic and beyond while enabling patients to access high quality care. For example, CMS could provide flexibility surrounding telehealth services to satisfy the face-to-face requirement in certifying eligibility for Medicare home health services during the public health emergency and ensuring that the certification process is streamlined and minimizes the paperwork burden for practicing physicians.

Supervision of Diagnostic Tests by Non-Physician Practitioners and Scope of Practice

Ordinarily, diagnostic tests in Medicare Part B are physician services that can be ordered by physicians and certain non-physician practitioners (NPPs), consistent with the scope of their state laws. Medicare

[2] Pub. L. 116-136, March 27, 2020.

regulations only allow a physician to supervise diagnostic tests paid under the Physician Fee Schedule (PFS). Nurse practitioners (NP), clinical nurse specialists (CNS), physician assistants (PA), and certified nurse-midwives (CNM) are unable to supervise diagnostic tests. NPs, CNSs, PAs, or CNMs may provide diagnostic tests "incident to" a physician's professional services, to the extent authorized under the non-physician practitioner's state scope of practice. The Medicare regulations are silent as to whether NPs, CNSs, PAs, or CNMs may supervise others when furnishing diagnostic tests.

The AMA reiterates its support for physician-led teams that integrate the strengths of non-physician practitioners and that use a team-based, shared decision approach to benefit the patient. This extends to the supervision of diagnostic tests. Expanding the scope of practice of nurse practitioners may increase the cost of care due to unnecessary orders for diagnostic imaging studies such as x-rays, and an increased number of biopsies as compared to physician-led teams. Thus, while CMS allowed for NPs, CNSs, PAs, and CNMs to order, furnish directly, and supervise the performance of diagnostic tests consistent with their state scope of practice during the COVID-19 PHE, the AMA does not believe this is the right approach to address non-COVID-19 diagnostic testing. Diagnostic testing for conditions requires extensive medical knowledge and a whole-person approach to testing. Authorization for the expansion of diagnostic testing for NPs, CNSs, PAs, and CNMs diminishes the role of the physician as the leader of a patient's diagnostic testing and threatens to erode the important team-based approach so integral to patient care and treatment. **Since CMS has made this a permanent change, the AMA asks CMS to closely monitor the care delivered to patients under this expansion to determine how quality and efficacy are impacted.**

Pharmacists Providing Services Incident to a Physician's Service

The AMA appreciates CMS' clarification that pharmacists are included in the definition of auxiliary personnel under § 410.26. The AMA shares CMS' position that pharmacist services can be provided incident to, and under the appropriate level of, supervision of the billing physician or NPP. The services delivered by a pharmacist should be consistent with the applicable state scope of practice laws.

II. Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests

The AMA supports the temporary requirement that certain diagnostic tests must be ordered by a treating physician or NPP in order to be covered under Medicare.[3] The nature and volume of cases in the unprecedented COVID-19 public health emergency prevented individuals from having a physician or NPP encounter or referral before obtaining a COVID-19 diagnostic test. CMS also extended this flexibility to diagnostic tests for the influenza virus and respiratory syncytial virus, allowing patients to be tested without a physician or NPP order, and for those diagnostic tests to be covered.

While the referral for diagnostic testing is not required, **the AMA believes the COVID-19 test results should be provided to the treating physician in addition to the required notifications to the patient and the state and local public health departments.** The physician is responsible for the patient's total health and well-being and is best suited to discuss the results in light of the patient's other conditions. The physician is connected to the patient's previous medical history and can help the patient interpret the results and any necessary future course of action. Physicians remain a highly trusted source of information to many of their patients. As the transmission of COVID-19 continues via community spread

[3] § 410.32(a).

and is asymptomatic in most people, a patient's physician is an invaluable part of providing accurate, scientific information on how to prevent and treat this disease.

III. Opioid Treatment Programs

The AMA shares the goal of reducing the burden of harm from controlled substances, including opioid analgesics. The AMA's commitment to that goal remains and is strengthened during the COVID-19 PHE when individuals may be dealing with stress, anxiety, loss, and other health conditions. The AMA continues our advocacy efforts in support of patients with pain and those with a substance use disorder as well as broad support for harm reduction policies and practices that address the wide range of factors affecting patients.

During the COVID-19 PHE, CMS implemented policies to facilitate the ability of patients to receive opioid treatment and support services:

- Patients in Opioid Treatment Programs can receive therapy and counseling by telephone if the patient does not have access to video services.
- Patients in Opioid Treatment Programs can receive periodic assessments by telehealth or telephone if appropriate/necessary.
- Coverage of audio-only visits for patients who need contact with providers but lack the two-way telecommunications technologies is important during the COVID-19 PHE.

The AMA supports the CMS flexibilities for opioid treatment programs to deliver telecommunications-based evaluation and management (E/M) services to patients in their homes during the COVID-19 public health emergency. Patients who may have a communicable disease can avoid exposing others to it by receiving opioid treatment in their home instead of traveling to an opioid treatment program to receive services. This strikes the appropriate balance between critical OTP services patients need and mitigating their risk of exposure to COVID-19.

IV. Medical Education and Teaching Physician Rules

The AMA supports CMS' exceptions and adjustments which holds harmless additional, temporary beds from the calculations to determine indirect medical education (IME) payment amounts under the inpatient prospective payment system at teaching hospitals. COVD-19 required the temporary increase in hospital beds which if included in the calculation at hospitals, would cause an undue reduction in indirect medical education payments. The AMA also supports this temporary IME policy for inpatient rehabilitation facilities and inpatient psychiatric facilities and appreciates CMS' exception for the IME calculation.

The AMA supports and appreciates CMS' understanding and flexibility in allowing teaching hospital residents to work at other hospitals where there is a workforce shortage and need for their services without negatively impacting the graduate medical education (GME) payments. The parameters for this new regulation provide sufficient flexibility and guardrails to ensure residents are temporarily shifted to another hospital for the COVID-19 response and are connected back to their teaching hospital when conditions and staffing allow. This ensures medical residents can deliver much needed care during the PHE without their position at a teaching hospital being cut due to the financial loss that could otherwise be associated with their temporary relocation.

Additional Flexibility Under the Teaching Physician Regulations

Our AMA endorses the flexibilities to the "primary care exception" during the COVID-19 PHE for certain services provided by a resident without the physical presence of a teaching physician. The AMA supports the use of innovative models of clinical and educational work hour requirements and direct resident physician supervision via real-time interactive audio and video technology to optimize patient safety and competency-based learning opportunities during the COVID-19 pandemic. The expansion of direct supervision being delivered using real-time interactive audio and video technology and allowing the teaching physician to remote in will help to decrease the risk of unnecessary exposure for both the patient and the physician. The AMA further supports the teaching physician's ability to review the services provided with the resident either during or immediately after the visit.

Moreover, the AMA supports the expansion of the primary care exception to include all levels of office and outpatient evaluation and management (E/M) codes. The additional services eligible under the primary care exception when furnished via telehealth are also a positive adjustment to existing policy during COVID-19. Taken together, these policies will help facilitate essential learning between the teaching physician, resident, and patient during this COVID-19 public health emergency.

The AMA supports the additional services eligible for the "primary care exception" during the COVID-19 PHE. We also are in favor of CMS' decision to allow telecommunications technology medical decision making or time associated with the E/M on the day of services. The AMA is pleased that both new and established patients will be able to receive services that include telephone E/M services, transitional care management services, online digital E/M services, and office or other outpatient E/M visits. This is a welcome expansion since during this time, every physician should be utilized to their fullest extent to ensure proper patient care.

The AMA continues to support the limits on direct supervision by interactive telecommunications technology to exclude high-risk, surgical, interventional, and other complex procedures including endoscopies and anesthesia and does not have any additional procedures to add under the flexibilities that CMS has granted at this time.[4] Overall, the AMA believes direct supervision by interactive telecommunications technology, and the expansion of the primary care exception, are appropriate in the context of the COVID-19 public health emergency and applauds CMS for allowing these options to be used during this time.

V. Inpatient Rehabilitation Facilities

Section 3711(a) of the CARES Act provides flexibility for inpatient rehabilitation facilities (IRFs) that are unable to deliver therapy according to the "3-hour rule" (three hours of prescribed physical therapy, occupational therapy, speech-language pathology, prosthetics or orthotics therapy for at least five days a week) without exception during the COVID-19 PHE. Documentation in the medical record may be done when practical if a post-admission evaluation within 24 hours is not possible and the 3-hour rule is not feasible due to COVID-19 staffing issues or the need to maintain distance for infection control. The AMA

[4] CMS extended flexibilities under the following four regulations during the COVID-19 public health emergency: a teaching physician must be present during the key portion of any service or procedure if reimbursement is sought under Medicare physician fee schedule (§ 415.172), all levels of an office or outpatient E/M service in a primary care center (§ 415.174), interpretation of diagnostic radiology and other diagnostic tests (§ 415.80), and use of a one-way mirror, video equipment, or similar device for delivering psychiatric services (§ 415.84).

appreciates CMS' consideration of the circumstances to allow the waiver of the 3-hour rule and the further clarification that the waiver is without exception.

In this IFC, CMS notes the flexibilities for IRFs admitting patients in support of acute care hospitals are applicable before or during Phase 1 of the re-opening of areas and are no longer available during Phase 2 or Phase 3. The AMA acknowledges the COVID-19 PHE requires agility in health system planning and encourages CMS to remain flexible as various state and local communities see their COVID-19 hospitalization numbers surge. The approach to address hospital capacity related to the COVID-19 PHE will require greater coordination for the months to come.

VI. Payment for Audio-Only Telephone Evaluation and Management Services

The AMA strongly advocated for CMS coverage of the CPT codes for audio-only visits, as many patients need physician services but cannot participate in two-way, real-time, interactive audio and video visits. By allowing payment for audio-only evaluation and management (E/M) services (telephone calls) by physicians for CPT codes 99441 through 99443, and by non-physician practitioners for CPT codes 98966 through 98968, many patients have been able to continue to receive important services from their trusted health providers. The AMA commends CMS for quickly allowing audio-only for services during the COVID-19 PHE, including for new patients. The AMA also deeply appreciates that CMS increased payments for these services to be equivalent to in-office visits. **The AMA continues to stress that physicians should continue to be able to deliver E/M services by telephone after the PHE for patients who need a telecommunications-based service in the home but who do not have access to a video connection or cannot successfully use one.**

The Health and Human Services Office of the Inspector General issued its Policy Statement to notify physicians and NPPs that administrative sanctions would not be imposed for reducing or waiving any-cost sharing obligations for federal health care beneficiaries for a large range of services, including telehealth services. The lack of sanctions does not prohibit a provider from collecting a cost-sharing amount; there may be providers who collect a cost-sharing obligation from a patient. As this is a new situation where Medicare beneficiaries may not be used to being charged for audio-only services from their providers, the AMA looks to work with CMS for ways that providers can notify patients of the intent to collect a cost-sharing amount before a charges accrue unbeknown to the patient.

VII. Flexibility for Medicaid Laboratory Services

The AMA recognizes the efforts CMS has undertaken to provide services to Medicaid beneficiaries during the COVID-19 PHE. CMS amended Medicaid laboratory service regulations to allow greater flexibility for the administration and coverage of COVID-19 tests. This includes coverage of tests administered in non-office settings and for self-collected COVID-19 tests. CMS covers in vitro diagnostic testing for the COVID-19 virus, including serological tests for COVID-19.[5] CMS has provided flexibilities to help prevent the spread of COVID-19 and to reduce obstacles to Medicaid coverage for administering and processing of tests in alternative settings besides an office, a similar facility, or a clinic. The AMA appreciates that CMS has not imposed any cost-sharing for COVID-19 tests for Medicaid beneficiaries, which could hamper access to testing.

[5] This requirement was enacted in section 6004(a) of the Families First Coronavirus Response Act, amended by section 3717 of the CARES Act and is incorporated into section 1905(a)(3)(B) of the SSA.

The AMA reiterates its strong advocacy on behalf of Medicaid patients and providers to receive commensurate services as other populations to address the COVID-19 PHE. The AMA supports providers receiving COVID-19 diagnostic testing results for Medicaid patients. Similarly, the AMA has stated physicians should receive the clinical laboratory results from COVID-19 diagnostic tests for Medicare patients.

VIII. Merit-based Incentive Payment Systems Qualified Clinical Data Registry Measure Approval Criteria

We greatly appreciate CMS delaying the 2021 Qualified Clinical Data Registry (QCDR) testing requirement. The AMA believes the timeline CMS finalized in the 2020 Medicare Physician Fee Schedule was overly aggressive and further challenged by COVID-19. We understand CMS' desire that all QCDR measures demonstrate reliability and validity, but we believe the new measure testing requirement will continue to be difficult for QCDRs to adhere to, particularly as the country continues to grapple with COVID-19. Taken together, the AMA believes the short timeline is infeasible. **Therefore, we urge CMS to gradually implement the requirements and continue to monitor the impact COVID-19 may have on QCDR testing, which is heavily reliant on data.** It is our understanding that many QCDRs have paused accepting data from physician practices or are receiving limited data due to COVID-19.

There are also legal delays that can impact the timeline for QCDR testing. It can take several months to execute a QCDR testing contract with a testing vendor. There is also a limited number of testing vendors due, in part, to the large number of measures now required to undergo QCDR testing. The AMA is concerned that the current number of testing vendors will be unable to support the increased demand. **Therefore, we have the following recommendations to handle the new testing requirement:**

- We recommend that CMS allow a grace period with existing QCDR measures. Some of the existing QCDR measures have been approved and in use for up to six years. Alternatively, measures that require testing could be prioritized based on uptake. For instance, measures reported by the majority of QCDR participants could be tested first, followed by the remaining measures in subsequent years.
- For new or substantially modified measures, we recommend CMS provide provisional approval for these measures, for at least two years, for use by QCDRs under MIPS, with the requirement that testing data be submitted the following year. This also would allow data to be collected on the measures and allow for more robust measure testing.
- We recommend a temporary exemption from testing requirements for any measure for which CMS requests harmonization or modification prior to use. Testing modifications prior to implementation would not be feasible given the timeline and should follow our same recommended policy on testing new measures.

Our recommended changes make the timeline to implement QCDR testing much more feasible as it takes substantial time to test measures, especially new measures for which there are no data readily available, so practices continue to treat COVID-19 and focus their efforts on re-opening.

IX. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic

The AMA supports the CMS interim policy which does not enforce the clinical indications for therapeutic continuous glucose monitors in Local Coverage Decisions during the COVID-19 PHE. Ultimately, **the AMA prefers a standard, National Coverage policy that would allow for therapeutic continuous glucose monitors.**

X. Time for Level Selection for Office / Outpatient Evaluation and Management Services Furnished Via Telehealth

We applaud CMS for taking the significant step to apply the CPT office visit code level selection and documentation guidelines concept to telehealth office visits during the PHE. The application of the 2020 CPT definitions, both for medical decision making and total time on the date of encounter was a positive step to eliminate confusion and to assist physicians in eliminating administrative burden. The AMA is engaged in ensuring an effective implementation of the new 2021 office visit codes and guidelines on January 1, 2021. This positive change for telehealth visits during the PHE will position physicians to be familiar with reporting based on time or medical decision making.

XI. Updating the Medicare Telehealth List

The AMA supports the updated list of Medicare telehealth services for the duration of the COVID-19 PHE. In comments submitted on the first COVID-19 IFC, the AMA made a number of recommendations for continuing coverage of Medicare telehealth services beyond the COVID-19 PHE. These recommendations include: continuing to allow patients to receive telehealth visits and treatment services in their homes; if the telehealth services are equivalent to in-person services, continuing to pay equivalent rates; as discussed previously, continuing to pay for the CPT codes for audio-only visits; maintaining specialist services like emergency medicine and critical care on the Medicare telehealth list; continuing to allow direct supervision to be provided via telehealth; and expanding the ability to provide Medicare Diabetes Prevention Program services through a virtual modality. Substantial additional detail on these recommendations is provided in the earlier letter.

The ability to manage patients' care via telehealth during the PHE in all areas of the country, not just rural areas, and to provide telehealth services to patients in their homes instead of requiring them to travel to other qualified originating sites has been invaluable and transformative. We deeply appreciate CMS' partnership and engagement in facilitating this transformation in care and strongly urge the agency to maintain these policies beyond the PHE.

In addition to these telehealth coverage and payment policies, the AMA also supports including smart phones in the definition of *interactive telecommunications* system as a method of broadening the scope of technology modalities available to a patient to receive health care. However, we note that physicians are obligated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to safeguard the privacy and security of protected health information and, accordingly, may select software or a telemedicine platform that is not compatible with a smart phone. Physicians should not be penalized for selecting software that complies with HIPAA, even if that results in patients not being able to use their smart phones to access such platforms.

XII. Payment for COVID-19 Specimen Collection to Physicians, Non-Physician Practitioners and Hospitals

The AMA appreciates that CMS updated its payment for COVID-19 clinical diagnostic testing in a number of settings, including physician offices. In the March 31, 2020 Interim Final Rule with Comment,[6] CMS provided payment for specimen collection and a travel allowance when independent laboratories collect specimens for COVID–19 clinical diagnostic laboratory testing from beneficiaries who are homebound or inpatients not in a hospital. Effective March 1, 2020, CMS has remitted payment of $23.46 for a specimen collection for COVID-19 testing for homebound and non-hospital inpatients, and payment of $25.46 for individuals in skilled nursing facilities. The March 31 IFC did not include a provision to pay for specimen collection for COVID-19 clinical diagnostic laboratory testing from patients in a physician's office or hospital.

The AMA supports and is appreciative of CMS' payment of $23.46 for COVID-19 specimen collection for established patients in a physician's office. This is an important effort to support COVID-19 testing and to pay physicians for part of the costs of administering the test. We support CMS' decision to use CPT code 99211 for COVID-19 testing. While CPT code 99211 is routinely used for established patients if services are furnished by ancillary staff and a face-to-face visit with the physician is unnecessary, CMS has also allowed this code to be used for new patient specimen collection during COVID-19. This is a welcomed update that the AMA appreciates, as it will allow physicians to care for and respond to patients who need to receive a diagnostic test.

XIII. Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency

CMS allows a set of remote patient monitoring (RPM) services for new and established patients during the COVID-19 PHE. CMS has modified its coverage policy for the CPT codes for remote patient monitoring of patients with an actual or suspected case of COVID-19 when monitoring lasts less than 16 days, but at least for 2 days. This is a positive change, as patients are not required to be monitored for the longer 30-day duration. The AMA appreciates CMS' actions to shorten the time a patient must be monitored, as it does not obligate resources for what may be a longer duration than necessary.

The IFC notes that the RPM services include two CPT codes for self-measured blood pressure monitoring (SMBP), one for patient education and training in SMBP and one for collection of data on SMBP readings. The AMA asks CMS to also cover home blood pressure monitors during the COVID-19 PHE and beyond. Hypertension places patients infected with COVID-19 at greater risk of severe disease impact. Home blood pressure monitoring is vital to achieving and maintaining blood pressure control, which can in turn reduce the risk of stroke, chronic kidney disease, and other serious health conditions. Evidence from meta-analyses of randomized trials indicates that self-measured blood pressure monitoring is associated with a reduction in blood pressure and improved blood pressure control (see https://www.ahajournals.org/doi/10.1161/CIR.0000000000000803). The clinical recommendation is to use a BP measurement device validated for clinical accuracy. The AMA believes coverage of home blood pressure monitors will facilitate more coordinated patient care.

[6] 85 FR 19256 through 19258. Published on April 6, 2020.

The AMA believes health technologies should be used to empower individuals, address patients' full range of health needs, promote healthy behaviors, and facilitate the improvement of health for individuals, families, and communities. To facilitate this, digital health technology and RPM services must capture, manage, and communicate information in a similar format using consistent terminology and measurement. This is particularly important as physicians incorporate patient-generated data and remote monitoring information into their decision-making processes and manage comorbid or chronic conditions from afar. The AMA believes coverage of home blood pressure monitors will facilitate more coordinated patient care.

Conclusion

We greatly appreciate the opportunity to share the views of the AMA regarding the Medicare and Medicaid basic health and exchange program policies in response to the COVID-19 Public Health Emergency Interim Final Rule with Comments. If you have any questions please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD