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July 9, 2020

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 Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735-P; 85 Fed. Reg. 32460, May 11, 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 the Fiscal Year (FY) 2021 Proposed Rule for the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System (LTCH PPS). Our detailed comments are below.

In summary, the AMA urges CMS to:

- Consider and plan for possible disruptions and complications from the rapid schedule for adoption of electronic health records during the 2022 Promoting Interoperability Program reporting period;
- Streamline the Promoting Interoperability Program to be less burdensome on physician practices and more meaningful in measurements collected, such as simplified attestation statements from electronic health record vendors;
- Prioritize how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. The AMA continues to have concerns and does not support inclusion of opioid measures that are based on limiting dosage or duration. The AMA believes that the current approach to address the epidemic of opioid-related overdose deaths through quality measurement has been too narrowly focused on preventing and/or reducing opioid use in the absence of addressing the larger clinical issue—ensuring adequate pain control while minimizing the risk toward opioid use disorder;
- Study variances in confidential reporting of stratified data on social risk factors and other methodologies that may yield conflicting information, especially if CMS moves to publicly report the information;

- Review, study, and refine the hospital readmission reduction program for negative, unintended consequences due to emerging evidence that it may be contributing to patient harm;
- Evaluate each novel technology on a stand-alone basis to determine whether it meets criteria for add-on payments for new services and technologies, particularly as the technology relates to artificial intelligence, algorithms, or software; and
- Implement positive steps to address the challenges faced by medical residents who are impacted by hospital and program closures.

Please see our detailed comments below on the following topics:

- I. Promoting Interoperability Program
- II. Hospital Inpatient Quality Reporting (IQR) Program
- III. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures
- IV. Hospital Readmission Reduction Program
- V. Innovation
- VI. Graduate Medical Education Issues

I. Promoting Interoperability Program

The AMA appreciates the opportunity to comment on the future direction of the Promoting Interoperability Program. The AMA believes it is important to focus on how to operationalize and strengthen the Promoting Interoperability Program, and welcomes the opportunity to provide feedback on the evolution of the Program.

Reporting Periods in 2022

The AMA supports CMS' proposal to extend continuous 90-day reporting for the Medicare Promoting Interoperability (PI) Program Electronic Health Record (EHR) reporting periods in 2022. We note that the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology's (ONC) 21st Century Cures Act final rule established a new timeline for certified EHR product updates. Many EHR requirements go into effect 24 to 27¹ months after the rule's May 2020 publication date. Several of these changes, including new EHR product features, functions, testing, and compliance requirements will become effective during the 2022 PI reporting year. In our 21st Century Cures Act proposed rule comments, the AMA cautioned ONC against creating an unnecessarily tight timeline for EHR product design, development, testing and certification while at the same time requiring physicians and hospitals to purchase, implement, train, and use these products.

EHR vendors will require a considerable amount of time to make changes and comply with ONC requirements. ONC has also linked all EHR updates and changes to the current 2015 Edition EHR moniker. That is, since physicians and hospitals must use 2015 Edition EHRs to participate in PI, as soon as EHR vendors are required to have their products comply with the new 2015 Edition EHR definition, all physicians and hospitals must also use these new products to stay in compliance with CMS' rules. Said another way, because most physicians and hospitals are bound to the use of 2015 Edition EHRs through CMS program requirements, the 24-month timeline will require EHR vendor development and physician

¹ The extra time is from the recently added three-months of enforcement discretion.

EHR adoption, implementation, and use <u>concurrently</u>. EHR vendors require between 18-24 months before their products are available for purchase and installation by physicians and hospitals. Once health care organizations have entered into their vendor's implementation queue, they experience 12+ month timelines before EHRs are upgraded and installed. In addition, physicians and staff need time to train on new EHR functionality. Conservatively, this development, installation, and use cycle can take 38 months—14 months more than what ONC has provided. The AMA strongly urges CMS to plan for the inevitable disruptions and complications resulting from physicians and hospitals having to rapidly adopt new EHRs during the 2022 PI reporting period.

Query of Prescription Drug Monitoring Program (PDMP) Measure

The AMA supports CMS' proposal to continue the Query of PDMP measure as a voluntary measure for EHR reporting periods in 2021. We agree that in light of the variation in how physicians interact with PDMPs, it would be burdensome to require this measure in 2021 reporting and that more time is needed before the measure is made mandatory for performance-based scoring.

Future Direction of the Medicare Promoting Interoperability Program

The AMA supports CMS' goal of thinking creatively to reduce burden and promote interoperability. While we believe there are several opportunities for CMS to achieve these goals, we continue to believe a "less is more" approach will be the most effective. A fundamental component for the future direction of PI must include a reduction in physician reporting burden and more freedom in the choice of technology.

Leveraging vendor-provided health IT utilization data to facilitate physician reporting is one such concept worth considering. We explored this idea in our **QPP CY 2019 comments** and in our response to **ONC's EHR Reporting Program Request for Information**. Currently, physicians shoulder the capture, documentation, and reporting for all PI requirements. EHRs are still built to track and record the process physicians take to meet measure requirements—making physicians feel they are just "going through the motions to check a box." The PI Program is designed to compel physicians to "use" the EHR, and therefore prescribed EHR usage has become the focus of the program—contributing to physician reporting burden. A less burdensome approach would be to measure and analyze which EHR functions best serve patients and physicians.

For instance, a physician could provide a simple "yes/no" attestation to a health information exchange (HIE) measure in PI. Their EHR vendor already documents and could report on the actual functionality the physician used to accomplish the HIE measure. Questions that an EHR vendor could report to achieve the intended purposes include:

- Was Direct used (identifying the usefulness of that EHR function)?
- Did the physician's query find unique patient records (identifying patient matching/record completeness issues)?
- How many "places" did the system need to search (providing emphasis on HIE frameworks such as the Trusted Exchange Framework and Common Agreement [TEFCA])?
- Was any information discoverable but "blocked" (helping identify information blocking Actors)?

Instead of requiring the physician to do the work of documentation, the EHR vendor-reported data could expose health IT system efficiency, whether the EHR accommodated the needs of the physician, whether

the EHR contributed to or detracted from patient care, areas where federal policy could address gaps, and whether the EHR supported the goal of interoperability—all of which are missing right now.

Reduce Burden and Burnout Through an Attestation Approach

The AMA appreciates CMS' continued engagement with physicians in burden reduction efforts. However, a new direction for the PI Program will require CMS to transition away from prescriptive physician measurement. Currently, numerator and denominator reporting devalues clinical care, forcing physicians to distill their medical practice down to a simple mathematical fraction. Too often the rich clinical information generated from the physician-patient narrative is clouded by unnecessary additional "note bloat" in order to score PI points. **All PI measures should therefore transition to "yes/no" attestation. This must be done to put patients over paperwork.** Any additional data on EHR use should be provided by the health IT vendor as previously discussed.

Weaving physician yes/no attestation with vendor-provided reporting would be a powerful combination. It would reduce physician burden, facilitate return on investment (ROI) discussions, and more accurately represent the real-world use of technology. The Health Information Technology for Economic and Clinical Health (HITECH) Act permits a professional to satisfy the demonstration of meaningful use of certified EHR technology (CEHRT) and information exchange through attestation. HITECH also permits reporting via "other means specified by the Secretary," granting the Secretary the authority to allow third-party-supported physician attestation. In addition, the AMA has worked with medical specialty associations to generate strong support for this strategy.

Removing the burden of PI reporting will also help alleviate physician burnout related to EHR use. Continuing to require prescriptive PI measurement detracts from clinical relevance of the patient encounter, adds burden, and focuses PI participation on documentation, reporting and compliance rather than improved patient outcomes. Furthermore, technology continues to evolve, and current PI measures are likely to become quickly outdated or fail to promote innovative uses of digital health tools. Said another way, today's 2020 PI measures are still tied to the legacy of Meaningful Use (MU). Given the Administration's focus on Patients over Paperwork and emphasis on reducing physician burden, measures that track and monitor physicians' use of EHRs should be abandoned.

CMS should create broad categories of PI objectives allowing physicians to attest "yes/no" to the use of CEHRT to achieve those categories. This will provide flexibility for patients and physicians to efficiently test new uses of technology—identifying what does and does not work while encouraging the use of EHRs. For example, CMS could create an objective called "Chronic disease management enabled by digital medicine." Measures could be developed that support physicians using not only emerging CEHRT functionalities, like application programing interfaces (APIs) and patient-generated health data (PGHD), but also could promote the use of digital health tools, such as remote patient monitoring services. We stress, however, that absent a yes/no attestation approach, any new objectives and associated measures should be optional to provide additional opportunities for physicians to be successful in the PI Program.

We also note that PI is not the only lever CMS has to drive interoperability, nor is it the most powerful. Physician compliance with MIPS information blocking requirements, ONC information blocking regulations, TEFCA, and the Health Insurance Portability and Accountability Act (HIPAA) patient right of access are themselves far better mechanisms to drive interoperability and promote patient access while reducing federal regulatory burden. The Administration's emphasis is clearly focused on comprehensive and bold regulation to move interoperability forward. **CMS tying PI to a legacy MU program anchors**

all of HHS and the Administration to a fundamentally flawed policy, a policy that is also tied to an EHR grant program that no longer exists. Meaningful use was intended largely to ensure physicians adopted and used EHRs. Since there are no funds involved, and adoption and use of EHRs is pervasive in the profession, it is illogical to link measures to whether EHRs are in use.

In sum, an innovative attestation-based PI Program, combined with new information blocking policies, will give physicians new freedom to choose the technology they want to use and how to use it—better supporting patient care and long-term wellness. The future direction of PI is prioritizing an attestation-based approach that reduces provider burden while getting physicians back to practicing medicine.

Flexibility in the Use of Technology

Physicians need a new pathway to adopt and use innovative technology. There are several emerging applications (apps) and technology platforms that leverage CEHRT but are themselves not CEHRT. For instance, a hospital could develop a suite of apps that connects a physician with social workers and community-based organizations (CBOs) helping families transition to stable housing. These apps would connect and pull information out of a CEHRT's fast healthcare interoperability resources (FHIR)-based API. However, many CEHRT products do not allow information in apps to be written back to the medical record. Physicians working within this app environment could "meet" several PI measures but would not receive credit since documentation is not done within the CEHRT or captured in a numerator. We should also not expect CEHRT to be built to facilitate every possible health or wellness scenario. Unfortunately, the tie of PI to CEHRT could disincentivize physicians from adopting new technologies that would aid in care coordination and patient engagement—physicians often need to spend their limited human and financial resources on technology that will help with PI compliance, even if doing so means forsaking more innovative and helpful technologies.

A new PI direction will require the flexibility for physicians to attest "yes/no" to using CEHRT, as discussed previously, while allowing for the use of technology that *interacts* with CEHRT to count toward PI. Doing so would engage clinicians who are non-patient facing that are currently exempt from the category (e.g., radiologists who use imaging equipment, but not EHRs). It would also reward physicians who seek to utilize emerging health IT for patient care or contribute data for aggregation and quality analysis purposes. Limiting physicians to CEHRT functions for PI success is counter to the Administration's goal to promote a pro-competitive marketplace and leverage the private sector's innovation and creativity as outlined by the White House Office of American Innovation.² Furthermore, CMS has already permitted this type of measure with its *Query of PDMP Measure*; CMS here recognized the potential value of PDMPs even when not integrated with an EHR. CMS should take similar steps for other non-CEHRT.

II. Hospital Inpatient Quality Reporting (IQR) Program

Reporting and Submission Requirements for eCQMs

Beginning with FY 2024 payment (CY 2022 reporting), hospitals are to report four electronic clinical quality measures (eCQMs): three chosen by the hospital from among a list of eight possible eCQMs and

² <u>https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-announces-white-house-office-american-innovation-oai/.</u>

one required of all hospitals: the Safe Use of Opioids – Concurrent Prescribing eCQM. The AMA does not support inclusion of the Safe Use of Opioids – Concurrent Prescribing measure in the IQR program due to our ongoing concerns that this measure will not truly drive improvements in care, is not aligned with the Centers for Disease Control and Prevention (CDC) guideline, and may result in unintended negative consequences for patients, hospitals, and physicians.

Specifically, as the AMA stated in previous comments, the measure as currently defined lacks the precision needed to ensure that only those patients as specified by the clinical recommendations are included in the denominator. Considering the *New England Journal of Medicine* article by Dowell and colleagues³ published on April 24, 2019, the AMA believes that no measure addressing opioid use should be implemented in any federal program until each measure is reviewed against the guideline to ensure consistency with its intent. For example, the CDC clarified that particular guideline is applicable to primary care clinicians who treat adult patients for chronic pain. Measures that call for hard limits and lead to abrupt tapering or discontinuation of opioids for those who already receive these medications are not consistent with the guideline recommendations. In addition, the CDC clarified in a letter to three specialty societies on February 28, 2019, that the recommendations do not apply to those patients receiving active cancer treatment, palliative care, and end-of-life care, as well as those with a diagnosis of sickle cell disease.

On review of the latest available specifications, the denominator population must be refined to ensure that the right population of patients is captured consistent with the evidence. Without further refinement, the AMA believes that there is a significant risk for the performance of hospitals and their physicians to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of these concurrent medications, that is an indication of good patient care. This is predicated on the measure being precisely defined for the appropriate patients. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

Use of Opioid Measures

As CMS continues to consider how to handle opioid use duration prevention, the AMA reiterates our concerns and lack of support on opioid measures that are based on limiting dosage or duration. The AMA believes that the current approach to address the epidemic of opioid-related overdose deaths through quality measurement has been too narrowly focused on preventing and/or reducing opioid use in the absence of addressing the larger clinical issue—ensuring adequate pain control while minimizing the risk toward opioid use disorder. Quality measurement must focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. We

³ Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med. 2019 Apr 24. doi: 10.1056/NEJMp1904190. [Epub ahead of print] Dowell D. Clarification letter to NCCN, ASCO, and ASH on the CDC's Guideline for Prescribing Opioids for Chronic Pain. February 2019. Available at: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf. Accessed on July 2, 2020.

believe the CDC measures listed in the CDC Opioid Use Guidelines are too narrowly focused. The report of the HHS Interagency Pain Management Best Practices Task Force, for example, made a compelling case for the need to focus on patients experiencing pain as individuals and to develop treatment plans that meet their individual needs, not employ one-size-fits-all approaches that assume ≥90 MME for ≥15 days is an indication of overuse. Likewise, a CDC publication in the *New England Journal of Medicine*, "No Shortcuts to Safer Opioid Prescribing," expressed concern that its opioid prescribing guidelines have been misapplied and wrongly used to discontinue or reduce prescriptions for patients with pain, with some actions likely to result in harm to patients. The CDC has specifically called out the guideline's discussion of 90 MME dosages as having been misapplied, noting that the guideline's discussion of 90 MME dosages does not address or suggest discontinuation of opioids already prescribed at higher dosages, yet it has been used to justify abruptly stopping opioid prescriptions or coverage.

The CDC and HHS recently co-authored a *JAMA* viewpoint article on the risks of abruptly discontinuing opioids and have developed a patient-centered guide to assist clinicians with reducing the risks and improving outcomes related to opioid dose reduction and discontinuation among patients prescribed opioids to manage pain (particularly chronic pain). Finally, the CMS Overutilization Monitoring System already employs a thoughtful patient-centered approach to potential opioid overuse, requiring that Medicare Part D plans consult with the individual patient's prescribing physician(s) to understand and confirm the appropriateness of prescribed medications. **Therefore, we recommend that CMS develop measures that examine adequate pain control with appropriate therapies of which opioids may be an option.** Until such time that these broadly applicable measures are available, we do not support expansion of opioid use measures that are narrowly focused measures.

We also would like to highlight that many of the CDC measures, specifically the long-term opioid therapy measures, are duplicative of the National Quality Forum (NQF) measures, and we have the same concerns with the NQF measures. For more detailed analysis on the NQF measures, please see the <u>AMA's 2020 IPPS Proposed Rule Comments</u>.

Furthermore, according to IQVIA data, between 2013 and 2018, the number of opioid prescriptions decreased by more than 80 million—a 33 percent decrease nationally. Every state has seen a decrease in opioid prescriptions during that five-year period. The nation saw a 12.4 percent decrease—more than 20 million fewer prescriptions—between 2017 and 2018 alone. And total opioid dose strength has decreased by similar or greater amounts. Yet, there continues to be many disturbing reports of patients' access to opioid therapy being denied because of inappropriate misapplication of CDC's opioid prescribing guidelines, including policies of health insurance companies based on those guidelines. **The AMA strongly opposes basing measures on an arbitrary threshold that has been disavowed by CDC as a hard threshold.**

III. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures

The AMA supports the expansion of the confidential reporting of stratified data to the five additional measures in the Spring of 2020. We believe that these reports have potential to provide supplemental information to physicians and hospitals on the quality of care they deliver to Medicare beneficiaries and

⁴ Dowell, Deborah. et al. Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics The HHS Guide for Clinicians. Oct. 10, 2019. https://jamanetwork.com/journals/jama/fullarticle/2753129?resultClick=1.

may be useful for quality improvement efforts at the point of care. We caution CMS on any future proposals to make these reports available to the public as hospitals are just beginning to gain familiarity with them and additional experience must be gained. In addition, the differences in the results between these confidential reports and the stratified methodology used by the Hospital Readmissions Reduction Program (HRRP) could lead to confusion and may yield conflicting information that may not contribute to informing patients and the public. We recommend that CMS study these differences, the potential impact on decision-making each may have, and what efforts should be made to harmonize these approaches if and when they are made public.

We continue to urge CMS to improve data capture to better allow for more robust risk-adjustment related to social determinants of health (SDoH). Specifically, there is a need to move toward harmonization of assessment tools (including LCDS PAC), and definition of explicit linkages between data capture/representation and terminology standards to allow data aggregation and analysis across populations and systems. Examples include piloting of SDoH programs through the CMS Innovation Center (e.g., Gravity Project use case, United Health Group/AMA ESRD transportation use case) to measure improvement in outcomes, advance best practices in providing interventions and develop mechanisms that pay for data capture, analysis and resulting action. Data derived from assessment surveys, and the algorithms used to analyze those data, should be free of bias that exacerbates health disparities.

IV. Hospital Readmission Reduction Program

There is an urgent need to re-evaluate the HRRP as there is emerging evidence that the program and the associated measures may be leading to negative unintended patient consequences and no longer capturing the appropriate patient population due to the structure and timeframe of the measures. ^{5,6} We continue to encourage CMS to work with the AMA and the provider community to further streamline the hospital quality reporting programs to reduce physician burden and better understand the impact CMS policies have on readmissions and patient outcomes.

The Hospital-Wide, All-Cause Readmission (HWR) measure is also duplicative of the current set of condition-specific measures. During previous reviews of the evidence provided by CMS on the measure, no research was presented that demonstrated that hospitals can directly or indirectly impact readmissions within 30 days across the broad patient populations treated. This lack of evidence paired with the continued omission of social risk factors in the risk adjustment model leads us to have significant concerns regarding the use of this measure that holds hospitals responsible for all-cause, 30-day readmissions. The traditional approach of risk adjusting at the patient level may not be appropriate for measures where the measurement period includes care that is outside of the control of the hospital and a 30-day post-acute phase where the availability of community support and other resources will directly impact a patient's care. We believe that there may be community-level variables that affect the risk of readmission during the 30 days following a hospital admission but are not currently addressed. Measures that extend beyond the hospital stay or outside the locus of control of the measured entity should continue to have Safety Data Sheet adjustment addressed and analyzed at different levels (e.g., patient, hospital,

⁵ Graham, Kelly. Et al (2018). Preventability of Early Versus Late Hospital Readmissions in a National Cohort of General Medicine Patients. Ann Intern Med. Doi. 10.7326/M17-1724.

⁶ Gupta, Ankar, et al. Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure. JAMA Cardiol. 2017. doi:10.1001/jamacardio.2017.4265. Published online November 12, 2017.

and community). In addition, CMS should work with the developer to continue to explore new variables that are directly related to the community in which a patient resides, particularly given the Assistant Secretary for Planning and Evaluation report. As a result, we believe that our concerns fall under Factor 2—measure does not align with current clinical guidelines or practice. The AMA recommends that CMS revisit inclusion of the HWR measure in the HRRP.

Impact of COVID-19 on Quality Reporting and Pay-for-Performance Programs

The AMA appreciates the steps that CMS took in March 2020 to provide relief under the hospital quality reporting programs and the three pay-for-performance programs—HRRP, Value-based Purchasing (VBP) Program, and the Hospital-Acquired Condition (HAC) Reduction Program—in light of the 2019 novel coronavirus disease (COVID-19) national public health emergency. Hospital reporting of data for the fourth quarter of 2019 is optional, and data for the period from January 1, 2020 through June 20, 2020 has been excluded from these programs, including for measures calculated by CMS using hospital claims as well as data that would otherwise have been submitted by hospitals for this period.

CMS should now consider the impact of these COVID-19-related data exclusions on the reliability of measures used for the hospital quality programs. The AMA believes that performance periods for measures that include this reporting gap should not be included in the HRRP, VBP and HAC program scoring calculations and should not be publicly reported on Hospital Compare.

V. **Innovation**

Add -On Payments for New Services and Technologies

CMS uses a two-part process to determine if a service or technology is new and whether there should be an add-on payment. First, CMS has three criteria for a new medical service or technology to receive add-on payments under the IPPS: (1) service or technology must be new, (2) the service or technology must be costly such that the current reimbursement through the DRG rate is inadequate, and (3) the service or technology must demonstrate a substantial clinical improvement over the existing services or technologies. Obtaining a new U.S. Food and Drug Administration (FDA) approval does not necessarily render a service or technology "new" for receiving an add-on payment. Second, CMS evaluates whether a new technology is substantially similar to an existing technology based on three criteria: (1) whether the same or a similar mechanism of action is used to achieve a therapeutic outcome, (2) whether the product is assigned to the same or a different MS-DRG, and (3) whether the same or similar type of disease or the same or similar population is treated by the new technology. CMS emphasizes its criteria and its evaluation do not depend on the FDA's safety and efficacy, but instead on substantial clinical improvement in the Medicare population.

The AMA declines to offer specific comments on the 15 applications for new technology add-on payments for FY 2021 included in the IPPS LTCH letter. Instead, the AMA offers the following comments on the substantially similar criteria pertaining to the same or similar mechanism of action (criteria #3) and artificial intelligence (AI).

The AMA recommends that CMS refrain from making broad, sweeping determinations about technologies that use artificial intelligence, an algorithm, or software. New technology add-on payments require a dissimilar or different mechanism of action as compared to an existing technology. The AMA does not agree, as CMS suggests, that technology using artificial intelligence cannot have a new

mechanism of action where its main purpose is to replace or supplement human protocols or thought processes and where no such technology currently exists. Instead, the AMA believes CMS should evaluate each novel technology on a stand-alone basis to determine whether it meets the stated criteria for consideration.

VI. Graduate Medical Education Issues

The AMA applauds CMS for beginning to address some of the challenges that are faced by residents due to program and hospital closures. Overall, the AMA believes these proposed changes are positive steps that will help to address the challenges encountered by residents who are displaced by future hospital and program closures. However, the proposed changes do not address all concerns or potential situations of displaced residents. As a result, the AMA has made several recommendations for CMS to explore prior to its release of the final rule.

AMA Supports CMS's Proposal to Change the Definition of "Displaced" Residents

Current Medicare policy allows a temporary cap adjustment for hospitals that accept residents from a hospital or program that is closing. This temporary cap adjustment allows these hospitals to receive Medicare direct graduate medical education (DGME) and indirect medical education (IME) funding for these residents for the duration of their training. However, in order for this funding to follow the resident to the new program, the resident must be considered "displaced." Currently, the definition of a displaced resident is one that is "physically present at the hospital training on the day prior to or the day of hospital or program closure." As outlined in the AMA's letter to CMS regarding the closure of Hahnemann University Hospital, we believe the physical presence requirement creates an unnecessary burden on the hospitals, residents, and fellows involved in the closing. The physical presence requirement and the definition as stated are quite limiting, and do not represent accurate scenarios that many residents may face. Moreover, the current definition of a displaced resident has long excluded residents on clinical rotations in an alternative practice setting, residents that leave a hospital after its announced closure but before the hospital actually closes, and individuals that have matched at graduate medical education (GME) programs but have not yet started. As such, the AMA appreciates that this new proposed definition gives residents greater flexibility to transfer to new hospitals during the winding down phases of their current placements. Overall, the AMA supports the new definition of displaced resident and believes that this will help to ensure that all residents are included and supported during future hospital and program closures.

AMA Encourages CMS to Make the Proposal Retroactive

It is our understanding that some teaching hospitals, which accepted and trained displaced residents, have been denied a temporary cap increase because the residents were not onsite the day before or the last day of the hospital or program closure. This issue became particularly acute during the Hahnemann University Hospital closure when so many residents were displaced. The receiving hospitals accepted displaced residents in good faith with the promise that they would receive DGME and IME funding for the duration of the residents' training.

Therefore, we ask that CMS make temporary cap increases effective retroactively to 2015 in the final rule. This would enable hospitals that accepted residents who were unable to be onsite the next to last day or on the last day of hospital or program closure to receive a temporary cap adjustment and DGME and IME funding. Although we believe the number of residents who were not considered

displaced is nominal, making the proposal retroactive to 2015 would send a strong message of support for residents and the hospitals that train them.

The AMA Urges CMS to Provide Additional Support for Residents

As a result of the AMA's experience helping our members navigate the abrupt closure of Hahnemann University Hospital during the summer of 2019, the AMA urges CMS to work with the Accreditation Council for Graduate Medical Education to establish regulations that protect residents and fellows impacted by sudden program or hospital closure. These regulations should include:

- Notice by the training hospital, intending to file for bankruptcy within 30 days, to all residents and fellows primarily associated with the training hospital, as well as those contractually matched at that training institution who may not yet have matriculated, of its intention to close, along with provision of reasonable and appropriate procedures to assist current and matched residents and fellows to find and obtain alternative training positions that minimize undue financial and professional consequences, including but not limited to maintenance of specialty choice, length of training, initial expected time of graduation, location and reallocation of funding, and coverage of tail medical malpractice insurance that would have been offered had the program or hospital not closed; and
- Protections against the discrimination of displaced residents and fellows on the basis of sex, age, race, creed, national origin, gender identity, or sexual orientation.

The AMA supports CMS' proposed rule changes to help displaced residents when programs or hospitals close. However, we also urge CMS to continue to evaluate opportunities to afford the residents and fellows impacted by hospital closures and the receiving hospitals flexibility with regards to any funding requirements that may unintentionally hinder a resident or fellow's ability to find an appropriate position with another GME training program and continue their education. **The AMA urges CMS to expand upon its current proposed rule change and provide additional protections to those that will be displaced by future hospital or program closures.**

Conclusion

We greatly appreciate this opportunity to share the views of the AMA regarding the proposals, issues, and questions which CMS has raised in the 2021 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Proposed Rule. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

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James L. Madara, MD