

April 24, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8013
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Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
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Dear Secretary Azar, Administrator Verma, and Dr. Rucker:

The 21 undersigned organizations applaud the expeditious actions by the U.S. Department of Health & Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) to issue waivers and new rules that help healthcare professionals and facilities adapt to the needs of the coronavirus pandemic. We thank the Administration for the regulatory flexibilities provided thus far to support surgeons during this national public health emergency (PHE) to deliver safe, high-quality care to their patients and to assist their communities in mitigating the spread of COVID-19. We offer feedback below for consideration by HHS, CMS, and the Office of the National Coordinator for Health Information Technology (ONC) as the Administration explores additional steps to ensure that physicians and hospitals are equipped to effectively absorb and manage potential surges of critically ill individuals during this time of crisis.

Below is a summary of the recommendations in this letter:

CMS Quality Payment Program (QPP):

- Extend the Automatic Extreme and Uncontrollable Circumstances Policy for all Quality Payment Program (QPP) participants for the Calendar Year (CY) 2020 performance year to allow physicians time to rebuild their practices post-COVID-19.
- Delay the implementation of the new Merit-based Incentive Payment System (MIPS) Value Pathways (MVP) framework to reduce burden on physicians during the PHE and allow extra time for clear programmatic details to be developed.
- Do not publicly report QPP data for the 2019 or 2020 performance years.

CMS Final Rule on Advancing Interoperability and Patient Access to Health Data:

- Delay publicly reporting clinicians' responses to the Promoting Interoperability (PI) information blocking attestation on Physician Compare. The 2019 and 2020 performance years should not be reported.
- One-year delay in the policy that requires the public reporting of which clinicians were not able to update digital contact information in the CMS National Plan and Provider Enumeration System (NPPES).

ONC Final Rule on Interoperability, Information Blocking and the ONC Health IT Certification Program:

- Delay information blocking enforcement for at least an additional six months, which would make the information blocking policy applicable, at the earliest, within 12 months after the rule has been published in the *Federal Register*.
- Take into consideration the current PHE and any associated delays in the enforcement of the information blocking provisions when determining the appropriate type and implementation date of provider disincentives through future rulemaking.

QUALITY PAYMENT PROGRAM

On March 23, 2020, CMS extended the data submission deadline for the 2019 performance year of the QPP from March 31, 2020, to April 30, 2020, to offer relief for physicians whose practices have been impacted by the current COVID-19 pandemic. In the announcement, CMS also stated that the Agency will apply the automatic Extreme and Uncontrollable Circumstance policy for MIPS Eligible Clinicians who are unable to submit their 2019 MIPS data by the extended deadline, automatically reweighting the performance categories so that eligible clinicians receive neutral payment adjustments in the 2021 Payment Year.

In its April 2020 interim final rule with comment (IFC), CMS implemented policies for additional relief for QPP participants. The policies focused on amending the Extreme and Uncontrollable Circumstances policies of the Medicare Shared Savings Program and MIPS to ease the burden on additional physicians during the PHE and to ensure that they will avoid payment penalties associated with quality reporting programs in 2021. We appreciate that CMS has offered this relief to physicians for the 2019 performance year as physicians have shifted their focus to addressing the COVID-19 pandemic, but strongly urge CMS to begin re-assessing the reporting requirements for the 2020 QPP performance year.

Extend MIPS Extreme and Uncontrollable Exemption for 2020

In light of the PHE, we strongly encourage CMS to extend the MIPS Extreme and Uncontrollable Circumstances policies and exemptions to automatically apply to all QPP participants for the 2020 performance year, so that no payment penalties are issued during the 2022 payment year. In order to control and address the PHE, extensive resources and efforts are required from the entire healthcare industry, forcing an extreme shift in how care is delivered and what services and programs can be prioritized during this time. As the country and our health system begins to recover, many things will need to be considered and adjusted to ensure high-quality patient care. For example, hospitals and healthcare facilities will need to be cleaned and inspected, quality infrastructures will have to go through a time of reconstruction and adjustment to account for what was learned during the pandemic, and practices will need to determine what is necessary to restore revenue. We feel that it would be inappropriate for CMS to require physicians to invest in and ensure compliance with performance-based programs like MIPS, even if for an abbreviated performance period, while they work to restore their practices. Instead, the sole focus should be rebuilding the infrastructure of healthcare systems and quality programs without risk to hospitals and physicians. **Therefore, we ask that CMS suspend quality reporting for the remainder of the 2020 performance year to allow physicians enough time**

to rebuild their practices, systems, and processes in order to ensure safe and effective delivery of patient care. In addition, to account for the disruption of care caused by the PHE, we do not believe that CMS should resume benchmarking quality data until practices are functioning as they were prior to the PHE, as data for the 2020 performance year would not be a valid representation of the care that they typically provide.

While we believe that all physicians should receive neutral adjustments and not be penalized in 2020, we do understand that many physicians have already begun reporting MIPS data for the performance year. We ask that CMS consider ways to reward those who have already started reporting MIPS data in 2020, as well as those who voluntarily continue to do so throughout the year, to assist in the recovery of resources that may have been expended to participate in the program and to provide an incentive for clinicians to remain engaged in the program during this “gap year.”

We also strongly urge CMS to refrain from publicly reporting performance data in 2020. Although the data that CMS intends to publicly report this year is reflective of performance that took place prior to this pandemic, it will not assist patients with healthcare decision-making during this public PHE, at a time when access to care is disrupted, and physicians are serving in all sorts of non-traditional roles. Similarly, we do not believe it would be appropriate or fair to publicly report performance data collected in 2020 given the significant disruptions in practice and the inability for many practices to even comply with these programs.

Delay the New MIPS Value Pathways (MVP) Program

In the CY 2020 Physician Fee Schedule (PFS), CMS finalized the implementation of a new MIPS framework, MVP, to begin with the 2021 MIPS performance period (2023 payment year). The MVP framework was initiated with the intent to connect measures and activities across the four MIPS performance categories, incorporate a set of administrative claims-based population health quality measures, provide data and feedback to clinicians, and enhance information to patients. The MVP framework also aims to streamline MIPS reporting by focusing the number of required measures to best assess the quality and value of care within a particular specialty or condition. Despite the MVPs intent to improve MIPS, **given the current PHE and uncertainty around programmatic details of the MVP at this time, we strongly urge CMS to delay the implementation of the new MVP framework. While we fully support efforts to both streamline this program and make it more meaningful to clinicians, we also do not believe it is appropriate to start changing the rules of an already complex program at a time when clinician attention is diverted, and practices are struggling to keep their heads above water. Even once this pandemic slows down, practice patterns and resource availability will long be disrupted.** As stated in the previous section, it is extremely important to give physicians enough time to rebuild the infrastructure of their practices to ensure they can safely and effectively serve patients before requiring them to take part in programs that may put an unnecessary burden on them. **We also believe that a delay in the implementation of MVPs could be beneficial for CMS, as it would allow them additional time to work with stakeholders to more clearly develop the MVP program and adjust programmatic requirements based on lessons learned from the COVID-19 pandemic.**

CMS AND ONC FINAL RULES IMPLEMENTING PROVISIONS OF THE 21ST CENTURY CURES ACT

The CMS Final Rule on *Advancing Interoperability and Patient Access to Health Data* and the ONC Final Rule on *Interoperability, Information Blocking and the ONC Health IT Certification Program* were released concurrently on March 9, 2020, just as the COVID-19 pandemic began to reach the United States. As of April 24, 2020, the final rules have not been published in the *Federal Register* and are scheduled to be published on May 1, 2020. Additionally, in response to the COVID-19 PHE, on April 21, 2020 CMS, ONC, and HHS Office of Inspector General (OIG) announced a policy of enforcement discretion which will allow for various flexibilities regarding the implementation of final rules. ONC, CMS, and OIG note that they will continue to monitor the implementation landscape to determine if further action is needed.

We have supported the long-awaited interoperability regulations that work to increase patient access to data, expand care access, work toward the elimination of health disparities, address public health crises, and improve health outcomes. The CMS and ONC final rules go a long way to address the siloed nature of data living in electronic health records (EHRs), which hinders care delivery. The necessity of interoperability and increased patient access to data are increasingly apparent during the current pandemic. However, it is not possible to begin to understand, build, and implement the requirements in these provisions during the crisis. **Instead, we believe additional delays in the current requirements and recently added flexibilities are needed while the health system struggles to address the COVID-19 pandemic. During and after the PHE, systems shortfalls will be even more evident, and lessons learned from this pandemic will provide an opportunity for CMS, ONC, and other stakeholders to identify the new roadmap for interoperability in a post-COVID-19 health care system.**

CMS FINAL RULE ON ADVANCING INTEROPERABILITY AND PATIENT ACCESS TO HEALTH DATA

Our comments below focus on specific sections of the CMS Final Rule on *Advancing Interoperability and Patient Access to Health Data* that we believe could have the most direct impact on surgeons.

Public Reporting and Prevention of Information Blocking

Beginning in late 2020, and starting with data collected for the 2019 performance year, CMS will publicly report a "no" response from clinicians, hospitals, and CAHs to any of the three attestation statements regarding the prevention of information blocking in the PI Programs in the QPP. Physician responses will be posted on Physician Compare.

As noted earlier, we request that CMS refrain from public reporting any QPP data related to the 2019 and 2020 performance years since both years have been disrupted by COVID-19 and will not necessarily be an accurate or complete reflection of clinician performance during that time. This should include a delay in CMS' recently finalized policy to publicly report, starting in late 2020, the names of clinicians that may be information blocking based on how they attested to the PI information blocking statement in 2019. If CMS is unwilling to delay public reporting for 2019 and 2020 QPP data, at the very least, it should include a disclaimer on

the Physician Compare website that informs the public that COVID-19 has impacted 2019 and 2020 MIPS participation. The disclaimer should clarify that a lack of PI attestations, and/or other data anomalies, may not accurately reflect performance due to disruptions in practice caused by COVID-19 and because many clinicians were eligible for reporting exceptions under CMS' Extreme and Uncontrollable Circumstances Policy.

Provider Digital Contact Information

The Secretary required that CMS create a provider digital contact information index under section 4003 of the Cures Act. This index must include all individual health care providers and health care facilities, or practices, in order to facilitate a comprehensive and open exchange of patient health information. CMS has chosen to update the CMS NPPES to be able to capture digital contact information for both individuals and facilities. NPPES currently supplies National Provider Identifiers (NPI) numbers to providers (both individuals and facilities), maintains their NPI records, and publishes the records online. Health care providers are required to communicate to the NPPES any information that has changed within 30 days of the change. NPPES has been updated to include the capability to capture one or more pieces of digital contact information (i.e., direct address, Fast Healthcare Interoperability Resources (FHIR) server URL, query endpoint, or other digital contact information) that can be used to facilitate secure sharing of health information.

To ensure that the NPPES is updated with this information, CMS finalized its proposal to publicly report the names and NPIs of those providers who have not added digital contact information to their entries in the NPPES system. Reporting of names and NPIs will begin in late 2020. **Although we believe that a regularly updated provider digital contact information index is important for supporting enhanced interoperability, publicly reporting which clinicians were not able to update this information is an unreasonable requirement during the current PHE. Therefore, we request a one-year delay of this policy.**

Revisions to the CoPs for Hospitals and Critical Access Hospitals

In the final rule, CMS modified the CoPs to require hospitals, including psychiatric hospitals and critical access hospitals (CAHs), to send electronic patient event notifications of a patient's admission, discharge, and/or transfer (ADT) to another healthcare facility or to another community provider or practitioner. The requirement would be limited to only those Medicare- and Medicaid-participating hospitals and CAHs that possess EHR systems with the technical capacity to generate information for electronic patient event notifications. This provision imposes a new set of requirements related to the use of EHRs outside of the PI program for providers. In the initial "public inspection" copy of the CMS final rule published on March 9, 2020, this policy was scheduled to be applicable six months after publication of this rule, which will be published in the *Federal Register* on May 1, 2020.

However, on April 21, 2020, CMS announced that the previously finalized implementation policy will be extended for an additional six months so that the policy will be effective 12 months after the final rule is published in the *Federal Register*. We greatly appreciate CMS granting this extension because delaying the implementation of this policy will allow time for hospitals and providers to restore the ability to make sure the hospital is providing safe and

effective care. Only after hospitals restore core functions should they be required to focus on implementing this new CoP policy for sending electronic patient event notification of a patient's ADT. Additionally, delaying implementation of this provision will allow CMS to more carefully evaluate information sharing needs and the appropriateness of specific processes in the context of a PHE, which was not fully contemplated when these regulations were first written. **We also recommend that CMS meet with impacted stakeholders and evaluate the state of affairs in late 2020 to assess whether an additional delay is needed.**

ONC 21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING AND THE ONC HEALTH IT CERTIFICATION PROGRAM

Information Blocking

The 21st Century Cures Act defines information blocking broadly as any practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI) when the entity knows it is likely to do so. It also directs the Secretary to identify actions that would not be considered information blocking and provides OIG with both investigatory and enforcement authority over information blocking. Under the act, the OIG may issue civil money penalties (\$1,000,000 per incident) for information blocking conducted by health information technology (health IT) developers of certified health IT, health information networks, and health information exchanges. The OIG may also investigate health care providers for information blocking for which health care providers could be subject to disincentives.

Under the ONC rule, health IT vendors and providers ("actors") are generally expected to comply with the information blocking provisions within six months. However, ONC adopted a more flexible, phased-in approach to implementation than originally proposed whereby it finalized an additional information blocking exception that would allow actors, when responding to data access requests, to initially provide only a more limited set of data elements (i.e., data included in the USCDI¹). After 24 months following the publication of this rule, these actors would be required to share a broader set of EHI.

Although we appreciate the grace period in the final rule and the limited set of required EHI which will provide actors with more time and flexibility to adjust to the new information blocking paradigm, these policies still require compliance within six months. It is infeasible and inappropriate to expect actors to comply with, let alone comprehend, ONC's incredibly complex and confusing web of information blocking rules and exceptions during this PHE. Understanding these new rules will require an extensive output of effort and resources that healthcare providers simply do not have at this time. Similar to the concerns raised above regarding the CMS interoperability provisions, **it is essential to cut all unnecessary regulatory and financial burdens during the PHE. Therefore, we request at least an additional six-month delay for enforcement of the information blocking policies and exceptions, which would make these policies applicable, at the earliest, no sooner than 12 months after this rule has been published in the *Federal Register* on May 1, 2020. We also urge ONC to meet with impacted stakeholders and evaluate the state of affairs in late 2020 to assess whether an additional six-month delay is appropriate or whether more time is needed.** Additionally, it is noted by

¹ USCDI is a standardized, but limited, set of data elements --e.g., clinical notes and patient demographic information

ONC that civil monetary penalties (CMPs) will not be enforced until established through future rulemaking. On April 21, OIG released a proposed rule that sets forth policies related to the application of CMPs for health IT developers and other actors. As stated in the Cures Act, these CMPs generally do not apply to health care providers. However, if OIG determines that a health care provider has committed information blocking, it shall refer the provider to the appropriate agency for appropriate disincentives. In its proposed rule, OIG states that it will determine the appropriate agency and disincentives through future rulemaking. **We strongly urge HHS to consider the current PHE and our request to further delay enforcement of the information blocking provisions when determining the appropriate type and implementation date for provider disincentives through future rulemaking. We oppose any type of penalty (financial or other non-financial disincentive) imposed for information blocking until HHS has carefully evaluated the ability of affected stakeholders to understand and comply with these requirements.**

We appreciate the Administration's numerous actions in the last few weeks to address the COVID-19 pandemic and to afford flexibility to physicians as they fight this crisis on various levels. We ask that the Administration consider these additional recommendations to enhance steps already taken to support physicians as they work to provide the best possible care to their patients both now and in the future.

Sincerely,

American College of Surgeons
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American College of Osteopathic Surgeons
American Pediatric Surgical Association
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society for Metabolic and Bariatric Surgery
American Society of Plastic Surgeons
American Society for Surgery of the Hand
American Urogynecologic Society
American Urological Association
Congress of Neurological Surgeons
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncology
Society for Vascular Surgeons
The Society of Thoracic Surgeons