January 28, 2019

Alex Azar II
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 600E
200 Independence Avenue SW
Washington, DC 20201

Ref: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Secretary Azar:

Thank you for the opportunity to submit comments on the strategy report for reducing regulatory and administrative burden relating to health information technology (IT) and electronic health records (EHRs). America’s Essential Hospitals appreciates the Office of the National Coordinator for Health IT’s (ONC’s) work with other agencies within the Department of Health and Human Services (HHS) to identify ways to reduce regulatory burden associated with the use of health IT. Essential hospitals are committed to using health IT to improve the lives of their patients, including by using IT in population health efforts, telehealth to reach patients who face barriers to transportation, and EHR data to reduce unnecessary readmissions and improve outcomes. Despite these successes, burdensome regulatory requirements drain staff time and resources that hospitals could better spend on delivering high-quality, patient-centered care. As HHS works to reduce administrative and regulatory burden, we encourage the agency to revise existing federal programs, enabling providers to fully leverage the potential of health IT without the constraints of rigid program requirements.

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our 300 member hospitals provide a disproportionate share of the nation’s uncompensated care and devote more than 75 percent of their inpatient care and nearly 70 percent of their outpatient care to the uninsured and to patients receiving insurance through public programs. Our members provide state-of-the-art, patient-
centered care while operating on margins substantially lower than other hospitals—4 percent on average compared with 7.8 percent for all hospitals nationwide.¹

Essential hospitals’ commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing electronic patient information, including poverty, homelessness, language barriers, and low health literacy.

We appreciate HHS highlighting areas for burden reduction regarding clinical documentation; health IT usability and user experience; EHR reporting; and public health reporting. We urge the agency to provide more information on how it will leverage its authority to implement the recommendations outlined in its draft strategies. Further, HHS should consider broader areas for intervention beyond its recommendations. There are changes that ONC, in collaboration with other partner agencies in HHS, can make to existing programs that will free providers of excessive regulations and direct their resources to patient care. Below, we highlight areas in which HHS can offer additional flexibility to providers.

Clinical Documentation

1. HHS should work with stakeholders to identify how to ease the burden of cumbersome evaluation and management (E/M) coding documentation requirements.

We applaud the agency for recognizing the burden associated with arduous documentation requirements. The report references changes to Medicare documentation requirements finalized in the calendar year 2019 Medicare Physician Fee Schedule final rule. These changes were a positive step, but other payers must follow Medicare’s lead in streamlining documentation requirements if providers are truly to benefit from such changes. **HHS should work with stakeholders to encourage other payers to adopt similar changes.**

Under current coding rules, practitioners must justify the level of E/M visit for which they bill by following one of two sets of extensive documentation rules, known as the 1995 and 1997 guidelines. Both sets of guidelines have similar key clinical elements required to document a level of E/M visit: a history of the patient’s present illness, a physical exam, and medical decision-making. The Centers for Medicare & Medicaid Services (CMS) finalized a policy that allows practitioners to continue using the 1995 or 1997 guidelines or choose to document an E/M visit using only medical decision-making or time. America’s Essential Hospitals is encouraged that CMS acknowledged that the amount of time and resources practitioners must dedicate to following detailed documentation can detract from the time spent focusing on patient care. However, these policies alone will not reduce physician documentation burden because other payers still require the use of the 1995 or 1997 guidelines. Until other payers follow

CMS' lead and simplify documentation guidelines, practitioners must continue using the 1995 or 1997 guidelines or maintain two workflows—one for CMS' simplified guidelines and another for other payers' guidelines. **HHS should work with other payers and stakeholders in the provider community to identify ways to streamline documentation requirements and ensure practitioners can focus on patient care.**

2. **HHS should work to develop consistent standards for electronic prior authorization that allow seamless integration of such processes into EHRs.**

America's Essential Hospitals encourages HHS to identify processes to improve care coordination and facilitate prior authorization, while preserving providers' ability to prescribe and deliver lifesaving medications and services expeditiously. The report appropriately highlights some of the burdens associated with prior authorization, which still primarily takes place through traditional, paper-based means and is not fully automated. The delay in automatic prior authorization processes is largely the result of a lack of standards and the failure of developers to implement existing standards. The ability of a provider to expeditiously submit prior authorization documentation verifying the need for a particular medication or service will facilitate the provision of care and minimize unnecessary burden on clinical and support staff. Electronic prior authorization has the potential to streamline the prior authorization process, but as with any health IT advancement, there are multiple issues that HHS should consider before providers are ready to adopt electronic prior authorization. Requirements pertaining to electronic prior authorization should:

- minimize burden on providers;
- have clear, consistent, and mature standards;
- protect patient privacy and security of sensitive health information; and
- integrate into existing mechanisms, such as EHR systems and e-prescribing capabilities.

As with other processes that require the use of health IT, it is imperative to have mature standards and requisite testing of these standards. HHS should ensure rigorous certification criteria for and oversight of EHRs with built-in electronic prior authorization capabilities so software developers deliver functional, safe products. Mature standards also are critical to ensuring patient privacy and secure transmission of confidential patient health information. Recent cybersecurity threats in the health care space, including through ransomware attacks on providers, are a reminder of the need to ensure the security of new capabilities before rushing into implementation.

In addition, HHS should explore the current landscape of electronic prior authorization to ensure all stakeholders—from prescribers to pharmacies—have the capabilities to benefit from this technology. This would include assessing the extent to which electronic prior authorization is built into electronic prescribing functionalities in EHRs. Hospitals are required to electronically submit prescriptions through their EHR as part of the Medicare and Medicaid Promoting Interoperability Programs (PIPs). To minimize provider burden, electronic prior authorization should integrate into e-prescribing functionalities to streamline staff workflows and minimize redundancy.
EHR Reporting

1. HHS should ease electronic clinical quality measure (eCQM) reporting requirements until eCQMs are proven reliable and can be reported with minimal disruption to provider workflows.

CMS requires eCQMs reporting in the Hospital Inpatient Quality Reporting (IQR) Program and the PIPs. Before expanding the number of eCQMs hospitals must report in federal reporting programs, HHS should verify that these measures are reliable and valid and have accurate specifications. HHS should work with EHR vendors to make electronic reporting of measures a viable option for all hospitals. The data extracted from EHRs differ from the data obtained from chart-abstracted measures and, therefore, are not reliable for display in a publicly reported program. The report cites these issues, noting concerns with testing, workflow, standardization, and the accuracy of eCQMs. Due to the differences between data extracted from eCQMs and chart-abstracted quality measures, HHS should adopt a validation process and conduct robust testing to ensure data extracted from eCQMs are accurate and comparable to chart-abstracted information.

It would be premature to require electronic reporting before all measures are fully electronically specified and field tested. In general, electronic measures have specific requirements about what type of information should be documented; they require more standardization than non-electronic measures. Without providing detailed electronic specifications far enough in advance, many providers will not have enough time to update their reporting systems. Providers adapt their workflows to ensure meticulous entry of standardized data into their EHRs. However, it is a process that requires extensive training and resources. It is unwise to incorporate any electronic measure into a federal reporting program until there is enough evidence of its validity in the field to justify its inclusion as truly meaningful.

2. HHS should provide more flexibility in the scoring methodology of the Medicare and Medicaid PIPs.

The report alludes to the challenges providers have cited with the PIPs, including the all-or-nothing scoring methodology. HHS can take steps to alleviate provider reporting burden in the PIPs, such as reducing the minimum total score to satisfy the PIP requirements and allowing hospitals to attest to the measures that are most useful to their practices and patient populations.

In rulemaking last year, CMS removed minimum individual thresholds for measures in favor of a weighted-average scoring approach. CMS' new policy is to assign a weight to each measure in the program and calculate a score based on the hospital’s performance rate for each measure. In some respects, this approach is still all-or-nothing in that a hospital must report on every single measure in the program, even though there is not a minimum threshold for each measure. Penalizing a hospital that is unable to report on one or two measures is a disincentive to program participation. These rigid requirements often hinder the true promise of EHRs to empower providers to offer the most appropriate care.
Further, a hospital must receive on average a score of 50 percent on each measure to receive a total passing score of 50. A hospital can compensate for low scores on individual measures by scoring exceptionally high on other measures. However, the scoring methodology is skewed in favor of more highly-weighted measures, such as the health information exchange measures and the measure requiring hospitals to provide patients electronic access to their health information. In practice, a hospital must receive high performance rates on both health information exchange measures to reach the minimum required score. Expecting high rates of performance on these measures in the first year of Stage 3 is unrealistic. By lowering the minimum required total score, CMS will allow providers to focus on measures of importance to them, instead of dedicating resources to measures that might be difficult for reasons outside of their control, such as the inability of outside providers to send or receive a summary of care document.

Additionally, HHS can provide more flexibility in the PIP scoring methodology by awarding hospitals a base score for reporting on all the required measures. This would be in addition to any points awarded for a hospital's performance rate on specific measures. For example, hospitals could receive 20 of their total required points through a base score, which HHS would award to hospitals if they report a numerator and denominator for the required measures in the PIPs.

**Public Health Reporting**

1. Before requiring the use of prescription drug monitoring programs (PDMPs) in the PIPs, HHS should work with stakeholders to ensure PDMPs are integrated into EHRs and clinicians can access them with minimal workflow disruption.

Until HHS can act on the recommendations in the draft strategy, the agency should not require providers to report on the PIPs measure to use data from certified EHR technology (CEHRT) to query a PDMP. CMS finalized this measure in the fiscal year 2019 Inpatient Prospective Payment System rule—the measure would be voluntary in 2019 but required in 2020.

Essential hospitals are on the front lines of treating patients most affected by the opioid crisis and have implemented innovative strategies to reduce opioid dependence. As leaders in population health, essential hospitals continue to develop programs that prevent opioid misuse among the most vulnerable populations. They partner with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis. As key stakeholders in combating the opioid crisis, essential hospitals stand ready to implement practices that have proved effective in reducing opioid dependence.

The report notes issues with PDMP integration into health IT, as well as workflow disruptions caused by practitioners accessing a PDMP to check a patient’s opioid medication history. Our members have indicated to us that accessing PDMPs can be an arduous process that requires the provider to close out of the EHR and provide
credentials to log on to a state PDMP website. In other words, a provider cannot always seamlessly access information from a PDMP from within the EHR when electronically prescribing a medication.

We agree with HHS' recommendations to improve interoperability between health IT and PDMPs. PDMPs lack uniform adoption across states and providers. Due to varying state requirements governing PDMPs, their use is uneven across the country. Not all states require the use of PDMPs and one—Missouri—does not even have a PDMP. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data and difficulty in establishing standards for the use of EHRs to access PDMP data. There are no standards or certification criteria governing the use of PDMPs, so hospitals have no guarantee that their certified EHR technology will include the functionality to query a PDMP. It is premature to require hospitals to report on a measure requiring the use of a PDMP while HHS is working with stakeholders on recommendations related to PDMP integration.

2. HHS should work with policymakers to clarify and lift restrictions related to substance use disorder confidentiality requirements.

Essential hospitals have deployed innovative approaches to treat patients with opioid and substance use disorders, but they continue to face challenges. When patients visit doctors and hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use that need to be factored into treatment and prescribing. However, requirements imposed by 42 CFR Part 2 (Part 2) limit providers' use of patient substance use records for certain substance use treatment programs. Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care. As a result, many providers often learn of addiction problems only after an adverse event or an overdose. Part 2 regulations also might lead to a physician writing prescriptions for opioid pain medication for an individual without knowing that patient had a substance use disorder. Separation of a patient's addiction record from the rest of their medical record creates several problems and impedes safe, effective, high-quality substance use treatment and coordinated care.

Part 2 must better align with the Health Insurance Portability and Accountability Act so health care providers can ensure comprehensive, coordinated substance use treatment and care. The Substance Abuse and Mental Health Services Administration released a final regulation, as well as informational materials and fact sheets on its website, clarifying how Part 2 relates to the exchange of information between providers. However, these steps do not go far enough to mitigate provider concerns. **HHS should work with lawmakers to modify Part 2, allowing for appropriate levels of access for providers to have a complete picture of their patients' health.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.
Sincerely,

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