HEALTH INNOVATION ALLIANCE

October 31, 2022

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Washington, DC 20515

Rep. Larry Bucshon
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Rep. Kim Schrier
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Rep. Michael Burgess
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Rep. Earl Blumenauer
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Rep. Brad Wenstrup
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Rep. Brad Schneider
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Rep. Mariannette Miller-Meeks
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Dear Reps. Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider, and Miller-Meeks,

Thank you for the opportunity to comment on the state of Medicare Access and CHIP Reauthorization Act (MACRA). The Health Innovation Alliance (HIA) strongly supports updating Medicare to ensure efficiency in payments to providers and to improve health care delivery and patient outcomes, particularly through the use of common-sense technology and data.

HIA is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of health IT to improve health outcomes and lower costs. We strive for an interoperable, patient-directed health system where providers are emboldened, not burdened, by technology, and entrepreneurs are able to bring new products to market at the speed of innovation.

MACRA has been overly burdensome to providers, requiring a complex regime of reporting on the part of clinicians, practices, and facilities to determine payments, and to assess quality and value. The burden and volume of reporting quality measures is staggering, and measures tend to skew toward quantifying underuse. The result is to prioritize services that will result in a positive effect on quality scores and payment, rather than what may be ideal for patient outcomes. There remains a sizeable portion of providers serving Medicare populations that are exempt from MIPS altogether – even though mandatory MIPS participation has been waived for the past several years due to the pandemic. Despite this well-documented complexity, the

current system has failed to deliver the cost reductions and improvements in patient outcomes that Congress sought in the first place.

Medicare – and by extension Congress - has failed to maintain levels of provider reimbursement that adequately incentivize high-quality care. As we seek to further the transition toward value-based care, Congress should consider systemic reforms to MACRA. Congress should also ensure consistency and reliability in payment updates. Congress and providers alike should not perennially face looming payment cuts due to poor policies, poor planning, and poor implementation and management. HIA looks forward to working with your offices to improve MACRA and create a long-term solution to health care financing and provider reimbursement.

Advance Interoperability and Innovation

Providers cannot succeed in value-based payment models if they lack a comprehensive view of a patient's medical and claims history.

The 21st Century Cures Act made significant changes to the treatment of health care data, but more than five years have passed since it became law, and many of the provisions have yet to be implemented. While there have been tremendous gains that improve access, exchange, and use of health information, an unclear regulatory environment is stifling private sector advances to interoperability. The pandemic has highlighted major issues with sharing health care information, particularly with respect to public health. By improving adoption and functionality in existing systems like EHRs and expanding interoperability efforts to other areas of health care, like public health and medical devices, we will begin to approach a truly liquid environment of usable health information. Automated collection and sharing of patient data through connected devices and information management systems could shepherd in an era of new medical innovation and precision medicine. But this will be difficult if not impossible if CMS doesn't do its part.

Some requirements, including details on how information blocking will be enforced against providers, still do not have proposed regulations despite carrying an "applicability date" of April 5, 2021. Other requirements on health plans to stand up APIs carry unclear enforcement or fall under enforcement discretion until further, technical rulemaking is released. ONC recently released aspirational statements on how interoperability will improve health care by 2030, but for that to happen Congress must act now. Congress must ensure CMS enforces the information blocking and interoperability rules in the 21st Century Cures Act to help ensure providers can accurately assess, diagnose and treat patients and do well in value-based models.

Recommendation: *Congress must conduct oversight and link funding to CMS implementation of the Cures Law.*

In April 2022, HIA released its Interoperability Workgroup Report with specific recommendations and regulatory changes to accelerate the implementation of health care interoperability.[1] They include:

- Enabling data to work for patients and providers at the point of care,

[1] *Available at* https://health-innovation.org/s/HIA-Interoperability-Report.pdf.

- Leveraging state of the art medical devices to improve patient care,
- Establishing clear protections from HIPAA penalties for patient information requests,
- Informing medical research and innovation with better information,
- Standardizing, collecting, and using social determinants of health data,
- Improving public health data collection and reporting.

Recommendation: *Congress should take these recommendations and work to promote data interoperability in health care. These policies and others will accelerate the common-sense advancement of health care delivery through technology used in most other industries that have struggled to take hold in health care because of excessive regulation and cost.*

Clinical Decision Support. One area specifically is the regulation of Clinical Decision Support (CDS) Software. The Food and Drug Administration (FDA) released a final guidance in September outlining certain CDS functionalities that are and are not considered by the agency to be medical devices and subject to medical device regulations and approvals.[2] The country is facing an historic shortage of up to 124,000 providers by 2034, and the federal government should do everything it can to combat burdens and facilitate the practice of medicine becoming a more modern, technologically savvy profession that young people want to join.[3]

Recommendation: *Congress should closely monitor regulation of software such as CDS to ensure that providers have the tools they need to provide efficient care that is also up to date with the most recent guidelines and medical thinking.*

Promoting Interoperability. Additionally, the Promoting Interoperability Program should be modernized to ensure the program's value is not outweighed by the burdens it creates, or the program should be phased out in favor of new programs to advance the use of interoperable technology and data sharing in health care to improve care and care coordination. Providers should not be subject to measures that require actions from patients or anyone else other than the providers themselves. Measures like the View, Download, and Transmit criterion should focus on whether the capability is present, not whether a patient actually completes the action since only the patient can control that outcome.

Streamline Quality Measures and Reporting

A built-in barrier to MACRA's success is the complex and burdensome system of quality measures that assess clinicians and determine the reimbursement. The sheer amount of quality measures contributes to the significant amount of time that providers spend documenting patient encounters. The solution is two-fold: quality measures must be relevant, and they must be easy to report. Not every quality measure is useful to figuring out which clinicians are providing the best care. It is critical that each clinician is only reporting on the measures that are most relevant

[2] *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software.
[3] *See* https://www.aamc.org/media/54681/download

to their practice area and the services that they are providing. The goal should be to streamline measures to target actual improvement in outcomes and decrease the amount of "busy work."

One way to bring that about would be to require the Secretary to adopt measures that are practice-specific, including for non-physician providers. At the same time, reporting ought to be optimized, automated, and built into provider workflows so that providers don't spend, on average, 200 hours per year simply filling out MIPS paperwork, at a cost of $12,811 per physician.[4] According to the same study, 87% of physicians think that the added MIPS payments do not cover the associated reporting and documentation burdens. Clearly, reporting burden is a significant problem.

Recommendation: *Congress should require CMS not adopt any functionality or quality reporting measure that cannot be done electronically or within workflow. This will greatly reduce provider burden.*

Another major problem is that programs are currently seriously misaligned and provide an opaque picture of quality. Quality measures need to be integrated with the goal of providing a clearer, more holistic picture of the services and steps going into patient care and the results that level of care delivers. Actions to this end could be required of the Secretary – aligning measures that will provide a clear indication of what services and locations result in the best outcomes. Too many measures are process-based, and Congress should look to incentivize the development and maintenance of true, outcomes-oriented measures.

Recommendation: *Congress should update the MACRA quality measure framework to reduce the number of quality measures reported by specialty and focus those measures on overuse.*

Increasing Provider Participation in Value-based Payment Models

To succeed in attracting more providers to value-based payment models, several issues must be addressed simultaneously. However, the underlying principle should be that any quality measures, incentives, and rewards need to be grounded and linked to overarching goals for individual and system-wide performance improvement. Any national strategy to improve quality must include specific goals and activities in priority areas. Without clearly-defined goals and specified steps toward realizing them, the process and incentives therein become muddy, and end up creating burden for the sake of reporting, not improvement. At the same time, investments must be made in critical infrastructure that supports these specific improvement efforts. By allocating resources on the front end to support dedicated human, intellectual, or other capital for the specific purpose of supporting quality improvement, returns will be realized in the long run. One of the failings of MACRA has been focusing too heavily on the cost-savings too soon, rather than investing in the longevity of the shift toward value-based payments.

An example of this is the lack of recognition of infrastructure costs – health IT, quality development, measurement, and reporting – that is required of any provider, practice, or health system participating in MIPS or an APM. These cost-of-entry barriers mean that MIPS disproportionately impacts small health systems who do not have the resources necessary to

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[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8796897/#:~:text=The%20mean%20per%2Dphysician%20cost,physician%20on%20MIPS%2Drelated%20activities.

keep up with the significant time and financial burden that program participation necessitates. Medicare patients are often high-burden individuals who may require frequent visits and experience poorer health outcomes, which would not reflect well in many performance measures. In light of this reality, the base payment rates ought to be updated to reflect the fixed costs associated with the creation of an environment where all practices can continuously meet or exceed quality benchmarks across beneficiary types. Failing to adequately fund the infrastructure necessary for success sets practices up to fail.

One tangible suggestion is that if the model requires participants to undertake some level of risk – including capitated payments, upside- or downside- risk arrangements, and others – then waiving certain program requirements ought to be considered. Some requirements ought to remain, such as patient outcome standards and financial conditions. However, other normal conditions such as mandatory reporting on a slew of quality measures could be waived in order to significantly reduce provider burden. Such a waiver would be a powerful incentivize to drive clinician participation, by allowing them to be more directly responsible for the outcomes of their patients while lessening the burden of reporting.

A major struggle, especially due to data issues during the COVID-19 pandemic, has been providing clinicians with timely feedback on their performance. Recent suggested changes would have the effect of depriving providers of real-time information on their performance under the models. While certainly not intentional, the result is clinicians that are on the hook for their efficacy while having no idea how they measure up until it is too late to course-correct. This outcome should be avoided at all costs. All efforts, public and private, should incorporate real-time feedback to enable and encourage learning and continuous improvement. The National Academy of Medicine has explored such improvements extensively through their "Learning Health System Series"[5].

Recommendation: *Congress should require CMS to stand up a system that provides real-time feedback to physicians on performance.*

Long Term Funding

Finally, one of the most basic qualities of a successful value-based payment model that will make participation attractive is stable, long-term funding. While funding cannot be entirely predictable due to differences in performance, quality, and patient outcomes, making reimbursement more certain would attract providers that have so far been too wary of risk. This means that CMS would need a more stable long-term plan that is conveyed to stakeholders in advance, and that is then steadfastly implemented as it was laid out. In part due to the pandemic, there has been a dearth of such stability with respect to requirements and other policy changes with the MIPS and APM programs.

Recommendation: *Congress should provide stable, annual updates to provider payments, and vary payment based on risk.*

[5] https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/

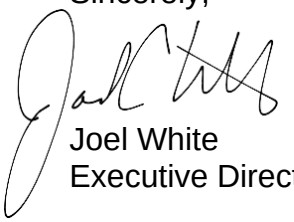
Incent Remote Care

Telehealth and other forms of remote care offer a great opportunity to extend access to care by connecting the patient and provider virtually from anywhere. It also has tremendous potential to improve patient care and to lower health care costs. The COVID-19 pandemic ushered in a new era of digital access through waivers of decades-old government restrictions, revolutionizing the delivery of care through expanded access to telehealth. We need to make sure this progress is not lost once the pandemic is over. Any changes to MACRA should include incentives for providers to offer remote care when applicable to harness the tremendous value proposition of keeping care out of expensive facilities and creating more frequent and convenient interactions between caregivers and patients.

Recommendation: *Congress should make telehealth a permanent part of the Medicare program. Any model that requires providers to assume risk should automatically qualify for program flexibilities to deliver care based on the provider's best judgement. Providers should be held accountable for patient outcomes, regardless of the method of care delivery.*

Thank you for your leadership on this issue and for the opportunity to provide suggestions on this important topic. I look forward to working with you to improve the Medicare program for clinicians and the patients they serve.

Sincerely,



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