Re: ASPE Request for Information - IMPACT ACT Research Study: Provider and health plan approaches to improve care for Medicare beneficiaries with social risk factors

Dear Deputy Assistant Secretary Destro:

The American Medical Association (AMA) appreciates the opportunity to respond to the Assistant Secretary for Planning and Evaluation’s (ASPE) Request for Information on the IMPACT ACT Research Study: Provider and health plan approaches to improve care for Medicare beneficiaries with social risk factors. Providing care to individuals and families that addresses both medical and social needs is integral to optimal health.

Overarching Question and General Questions

The Department of Health and Human Services (HHS), private payers, physicians, hospitals and others must work collectively to create a system that enables the collection and use of this information at the point of care and for communities, regions and across the United States. We support efforts to accelerate the consideration of social risk factors and associated social determinants of health (SDH) into the provision of direct patient care and population health management, and for measurement purposes. Our comments focus on the gaps in knowledge, resources, and/or data, particularly as those gaps impact individuals receiving care in small practices and those physicians and groups who serve in rural areas or underserved populations. The areas include:

- Delivery of services
  - Education on how to collect and document social risk factors and SDH including access to resources to address such factors in a manner that respects a patient’s autonomy and privacy;
  - Toolkits and resources for all health care settings and providers integral to identify, appropriately select and refer patients with social risk factors;
  - Legal restrictions that may limit a physician’s ability to successfully implement these practices; and
• Financial incentives or other investment and reimbursement methods to offset these costs for physicians.
• Data
  • Standardization of the required SDH data elements to enable consistent and reliable tracking of progress, integration into electronic health record systems (EHRs) and clinical registries, and for aggregation of the information for secondary uses such as measurement

Evidence and gaps in knowledge

The Deloitte Center for Health Solutions surveyed hospitals and health systems to assess current and future efforts around social risk factors. More than 80% of the hospitals and health systems currently screen those individuals who were hospitalized or identified as higher users of the system at a minimum. Just over 40 percent have a clear pathway to connect patients with needed resources with most being the larger hospitals and disproportionate share hospitals; however, 25 percent indicated that they did not have that capability. Even with higher rates of screening, most hospitals or systems reported that processes were not standardized or consistent across their patient populations and approximately 40 percent of the respondents report that they are not able to track the impact on health outcomes, cost and patient experience. The lack of sustainable dollars to support these initiatives remained a challenge for most and often required cobbling together funding from multiple sources such as state and federal agencies. While there is broad interest in integrating this information at the point of care, doing so requires significant financial resources and partnerships to implement effective strategies.

While the Deloitte study provides a snapshot of current approaches to SDH adopted by hospitals and health systems, the degree to which these issues are being identified and addressed in physician practices is less clear. Research funded by the Robert Wood Johnson Foundation in 2011 found that 85 percent of physicians concur that addressing medical and social needs are equally important and poorer outcomes are directly linked to unmet social needs. Regrettably, the majority reported that they did not feel adequately equipped to be responsive to these needs, limiting their ability to provide optimal quality care. This sentiment is further confirmed in a recent editorial by DeVoe and colleagues in which they concluded that integration of social determinants of health is not broadly implemented across primary care practices and there is little to no evidence to show how these data can be integrated into care effectively. These findings demonstrate that currently the ability for primary care, specialists and small practices to address social risk factors is limited.

There is emerging evidence indicating that investment in programs and initiatives focused on effectively addressing social risk factors can drive improvements in patient outcomes, result in cost savings to the system and positively impact a physician’s job satisfaction. A study by WellCare Health Plans and the University of South Florida found that health care spending was reduced for those patients with social

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needs by 10 percent compared to those whose needs were unmet. Another study demonstrated that
provision of resources that enable physicians to be responsive to their patient’s social needs is associated
with less levels of professional burnout.

Standardized Terms and Definitions

We believe that it is important to also standardize the definitions and terms to facilitate broad
understanding and communications across providers. For example, additional precision in terminologies
and definitions related to “dual eligible” versus “dual covered” is needed. Standardizing these terms
would enable accurate identification of patients at risk, particularly within EHRs, and prevent incomplete
capture of the patient population for measurement. Specifically, we have determined that there are no
clear definitions for “dual eligible” and “dual covered” due to state-to-state differences in Medicaid
eligibility, as well as the level of coverage each beneficiary may receive within these programs. These
nuances play an important role in understanding what services and treatments are covered versus those
that will require referral to other resources. In addition, an individual’s status can change over time and
currently we are limited in our ability to capture these variances electronically and longitudinally.

Beyond eligibility and covered status, there have been efforts to classify and target beneficiaries by zip
codes (and when available, zip+4 increases precision), but beneficiaries are transient and zip codes may
be changed by the United States Postal Service. Some rural areas, particularly in the Mountain West, do
not have assigned zip codes and it is unknown what percentage of the population is missed when we rely
on zip codes to target or risk-adjust based on social risk factors. Therefore, there is a need for further
understanding of the implications and stability of five plus four-digit zip codes as a marker of
socioeconomic risk.

Delivery of Services

The environmental scan and evidence review we conducted to respond to the Request for Information
(RFI) identified a key theme across the various national initiatives and regional collaborations targeting
this topic. Many of these health systems or health plans were successful in creating sustainable models
through partnerships with more than one organization within a community, and many established
relationships with a data analytics or information technology vendor. We believe that there may be
successful strategies, best practices and lessons to be learned from these entities to address the critical
gaps on education, toolkits and resources.

National Initiatives and Programs

The following are organizations and projects that have focused on standardized data collection and
provision of data at the point-of-care and for population health management from whom ASPE may
gather useful information and data.

Atrium Health Community Resources Hub (https://chscommunityresourcehub.auntbertha.com/) -

4 Pruitt Z, Emechebe N, Quast T, Taylor P, and Bryant K. Expenditure reductions associated with a social service referral
address patients’ social needs associated with lower burnout in primary care providers. J Health Care Poor Underserved.
Region-based online tool that allows providers and patients to identify potential solutions available in the community to address resource needs such as transportation, food pantries, and housing.

City Health Dashboard (https://www.cityhealthdashboard.com/) - Provides data on social determinants of health, patient outcomes, clinical care, and other measures on 500 cities across the United States.

Healthify (https://www.healthify.us) - Software solution focused on linking patients’ social risk factors with the necessary resources for health plans and health systems.

Health Leads (https://healthleadsusa.org/) - Organization that collaborates with hospitals and clinics to implement interventions at the point of care and within the community.

The Protocol for Responding to and Assessing Patients’ Assets, Risks and Experiences (PRAPARE) (http://www.nachc.org/research-and-data/prapare/) - Initiative to assist health centers and providers collect the social risk factor data needed to improve patient outcomes, particularly using EHRs.

NowPow (http://www.nowpow.com/) - Using data integrated into EHRs, this startup assists health systems to identify community resources based on the patient’s needs.

Selected Community and Regional Models

Geisinger’s Fresh Food Farmacy (https://www.geisinger.org/freshfoodfarmacy) - Program targeted to patients with diabetes who are food insecure and have higher HbA1c levels (above 8.0 percent) than is considered optimal who are referred by their physician for clinical interventions, education, and access to healthy foods.

Utah Alliance for Determinants of Health - Partnership of city, county, and state agencies and community organizations that seeks to develop a model for providing resources and support to address social risk factors such as housing instability, food insecurity, and other needs and improve patient health and reduce costs. (https://intermountainhealthcare.org/news/2018/06/new-alliance-seeks-to-promote-health-and-prevent-illness-by-addressing-social-determinants-of-health-in-ogden-st-george/)

UnitedHealth care - Awarded grants to several community-based organizations in Wisconsin to address food insecurity and provision of preventive health screenings such as dental and vision care. (https://newsroom.uhc.com/news-releases/unitedhealth-care-awards-1-95-million-in-grants-to-wisconsin-com.html)

States are also addressing social risk factors with just under 20 requiring Medicaid managed care plans to screen and refer patients with these factors. The majority of Medicaid managed care plans have initiatives to address social needs. The Center for Medicare and Medicaid Innovation State Innovation Models and the Delivery System Reform Incentive Payment initiatives also seek to leverage approaches for addressing the social needs of patients through partnerships and targeted projects within communities.6

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Barriers/Restrictions

The anti-kickback statute, physician self-referral law (Stark), and the civil monetary penalty (CMP) law are potential barriers to tailoring and delivering services to patients with social risk factors. Significant changes in our understanding of the impact of SDH on health, health care payment and delivery have occurred since enactment of the existing fraud and abuse laws. Numerous initiatives are attempting to align payment and care coordination efforts to improve the quality and value of care delivered. In addition, the delivery of care is undergoing a digital transformation associated with adoption of innovative technology. However, the fraud and abuse laws have not commensurately changed. The laws can have a negative impact on Medicare beneficiaries with social risk factors by inhibiting collaborative partnerships, care continuity and the engagement of patients in their care.

As discussed in the RFI, continuity of care requires smooth transitions to prepare for patients’ changing clinical and social needs. The Stark law may impede this continuity and these care transitions. Specifically, in certain circumstances, physicians are prohibited from employing promising care coordination strategies on behalf of their patients, e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient’s care among a hospital, physician specialists, or a primary care physician may induce future referrals to their own office to avoid an unnecessary readmission to the hospital. Instead, patients, in addition to dealing with the physical and emotional aspects of a disease or condition, often find themselves having to coordinate their own care in a fragmented and siloed system. Placing the obligation on the patient to know how to properly manage follow-up care without the assistance of their physician or care coordinator may have a negative impact on patient care, the physician-patient relationship, and on a physician’s ability to achieve high levels of performance for beneficiaries with social risk factors. This barrier can be overcome through creating an anti-kickback safe harbor and Stark exception to facilitate coordinated care.

Engaging patients in their care involves designing individualized care to promote the health of individuals in the community setting. Under the CMP, this engagement can include providing certain incentives that promote access to care (e.g., providing childcare during an appointment). However, the AMA is concerned about potential anti-kickback statute liability for these arrangements. For example, provision to beneficiaries of a dedicated mobile treatment plan app that facilitates daily engagement with the physician and ensures greater compliance with evidence-based treatment plans fit within the exception from remuneration under the beneficiary inducement CMP because it helps beneficiaries access care by improved future care-planning by their physician. However, even though this tool provides early intervention to avoid unnecessary hospitalizations and emergency room visits, the arrangement is still subject to anti-kickback statute liability because it may induce future referrals to the physician to receive coordinated care. This barrier can be overcome through creating a new anti-kickback safe harbor to cover this conduct or by issuing a law enforcement policy statement from the Office of Inspector General that meeting the requirements of the promoting access to care exception from the definition of remuneration from the beneficiary inducement CMP poses a sufficiently low risk of fraud and abuse under the anti-kickback statute.

Another type of beneficiary engagement that implicates the anti-kickback statute and CMP is the provision of incentives for wellness and managing chronic diseases (e.g., adherence to treatment plans and management programs). There is no exception under the CMP or the anti-kickback statute for this type of incentive. Thus, physicians cannot provide incentives for adherence without facing treble fines and jail time. Rewarding adherence can help some patients understand the important interactions between
lifestyle, socioeconomic position, disease, and prescribed treatment. Ultimately, validated programs could substantially reduce the cost of health care over time and help patients achieve better health and health outcomes and physicians achieve high levels of performance for beneficiaries with social risk factors. This barrier can be overcome by creating a new exception from the definition of remuneration under the CMP to include adherence to treatment plans and management programs.

Financial Incentives or Other Reimbursement Methods

Financial incentives or other vehicles by which physicians and other providers can offset these costs must be identified. Many of the activities, applications and other resources required are not currently reimbursed by Medicare or private payers. Alternative payment models are moving in the direction of addressing risk, but also largely do not cover activities and related services. Physicians are limited in their ability to provide free services unlike hospitals, which may apply the community benefit standard; yet, they are often well suited to identify and refer patients for these services during the course of routine care.

Data

There is growing evidence to support the integration of social risk factors and determinants of health into EHRs at the point-of-care, but challenges and barriers exist that must be addressed for successful and widespread implementation. The recent study by Gold and colleagues in three Pacific Northwest community health centers demonstrated that integration of these data into practice can be accomplished, but not without significant effort. While three barriers were explicitly identified, all related to the lack of data integration into clinical workflows in an efficient, meaningful way. For example, capturing the information on paper to then be manually entered into the EHR increased the burden. Display of relevant data in disparate sections of the patient’s record increased complexity and negatively impacted physicians and staff’s overall experience. It was also difficult for staff to identify and document resources to which a patient could be referred and follow-up, due to increased positive screening rates and unmanageable workloads.

The AMA believes that the data collection and aggregation of SDH must be standardized to the greatest extent possible to enable use within practices for quality improvement and across populations to monitor progress toward our desired outcomes. Collaborations involving frontline physicians, hospitals, community leaders, EHR vendors and others are needed to enable this standardization without compromising clinical workflows and patients’ privacy.

EHR and 2015 Edition Certified EHR Technology (CEHRT) Issues

These efforts will facilitate reliable and valid data that can be used for multiple purposes including performance measurement. All the factors mentioned previously are integral to the reliability and validity of the data for measurement and perhaps more importantly to enable us to develop the evidence needed to demonstrate a linkage between addressing these factors, improving outcomes and reducing costs.

Some larger EHR vendors have enabled social risk factor collection, often using electronic screening tools for data capture. However, there is no universal mechanism for collecting social risk factor data, nor

a definitive set of social risk factor data elements to collect. While the current landscape provides flexibility, and allows different individuals within the health care organization to capture social risk factor data, too much variation limits a delivery system’s ability to analyze SDH and related data from EHRs and other sources, and may limit the use and usefulness of the collected data. Furthermore, in terms of user navigation and overall usability, inconsistencies in social risk factor collection throughout the clinical workflow and encounter contribute to clinicians’ cognitive burden.8

Depending on an organization’s internal policies and available resources, or the sensitivity of the information, social risk factor data could be captured by behavioral health workers, nurses, or medical assistants. Individuals may feel more comfortable using a kiosk or online portal to enter sensitive information, such as domestic violence or abuse. Additionally, there are situations where the applicability of social risk factor information differs based on the medical specialty. For instance, health care organizations may identify a standard set of social risk factor indicators for collection; however, physician specialists or subspecialists may request additional unique social risk factor data, e.g., mental health and social stressors.9,10 Therefore, there is a need for customizable or “extendable” social risk factor tools to support patient care or health care operations.

Standards, such as Protocol for Responding to and Assessing Patients’ Assets, Risks, and Experiences (PRAPARE), consists of a set of national core and optional measures. While there is a freely available PRAPARE toolkit, which includes EHR templates, workflow diagrams, and implementation strategies, only a small number of EHR vendors support PRAPARE’s integration.11 Even for the EHRs that support PRAPARE, questions remain around the total lifecycle costs for implementation—including long-term EHR support, data analysis, and reporting. There is further concern about the cost EHR vendors are charging physicians to enable even this basic level of functionality and the fees to connect third-party applications that support SDH.12,13

Significant emphasis has been placed on the expected data exchange capabilities of the next generation of EHRs—including the ability to better support social risk factor and social determinants of health data. While the 2015 Edition of CEHRT products are required to support application programing interfaces (APIs), overwhelmingly EHR vendors are implementing read-only APIs focused only on the information required in the Centers for Medicare & Medicaid Services and the Office of the National Coordinator for Health Information Technology’s (ONC) common clinical data set (CCDS). Federal certification focuses on the EHR’s ability to support individuals’ access to only a small subset of patient information—acting

as an artificial high-water mark for EHR design. For example, the CCDS is a grouping of 20 data classes that is meant to act as a “floor” of data for certified EHRs. Yet, ONC has identified at least 50 additional data classes—including those considered social risk or SDH—that should be accessible electronically.\(^\text{14}\)

The ability for patients and physicians to have electronic access to the entire medical record is a core tenet in the Health Insurance Portability and Accountability Act (HIPAA) and the 21\(^\text{st}\) Century Cures Act. However, the lack of read and write capability, coupled with vendors limiting data to only the CCDS, contributes to the inherent weakness in 2015 CEHRT Edition EHRs’ APIs.

**Cybersecurity Challenges**

There is deep concern that our nation’s health care providers and patients have been insufficiently prepared to meet the cybersecurity challenges of an increasingly digital health care system. This will continue to be a concern as the tide of information, including on social risk factors and determinants of health continues to rise. The health care community must recognize that cybersecurity is not only a technical issue, but also a patient safety issue. The AMA recently completed a first-of-its-kind cybersecurity survey of 1,300 physicians.\(^\text{15}\) The top three cybersecurity concerns that physicians identified were interruption of access to an EHR, EHR security (including compromise of patient data), and general patient safety concerns. The survey results underscore the importance of considering the potential harm to patients and interruption to their care when conducting cost-benefit analyses of available approaches to data security, privacy, and interoperability. Cybersecurity is a national priority and physicians, other health care providers, and patients need tools to secure sensitive patient information in the digital sphere.

**Standardized Data Elements**

Due to a lack of standardization, there are challenges with the variability in coding social risk factor and determinants data. The multiplicity of data coding, beyond just social risk factors, contributes to the larger interoperability issue. Some of this can be attributed to health care organizations’ desire for flexibility; however, even the codes and regulations are inconsistent. In some cases, individual data elements can be represented by multiple codes in one terminology or multiple codes across different terminologies. This becomes challenging for EHR vendors who then are required to support different value sets. There is wide recognition that greater standardization would allow health care organizations to better analyze and interpret social risk factor data in clinical decision-making and would reduce some pressure on EHR design and development. This is also a necessity to advance interoperability.

Further, not all social risk information can be coded and free text fields are frequently used despite efforts by the organizations that manage terminologies, e.g., the World Health Organization (ICD), Regenstrief (LOINC) and SNOMED International (SNOMED-CT). Much of the data that are collected cannot be characterized by a given code, necessitating capture in free text. This becomes especially challenging when screening tools or surveys combine codified or yes/no responses with free-text fields to provide context, description, or further detail.

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One approach is to implement social risk factor and determinants data collection tools with a focus on a dimension of interest e.g., chronic disease or specific clinical domains like hypertension, diabetes and asthma. Starting with a priority set of patients or a smaller cohort allows both EHR vendors, health care organizations and the data standards and interoperability communities to work out technical difficulties, refine and improve clinical workflows, and facilitate scaling to larger populations.

Given the breadth and depth of these issues, multiple stakeholders including physicians and health care professionals, patients, vendors, standards-developing organizations and government agencies must work together in a collaborative fashion.

How AMA is contributing to a solution

The AMA’s Integrated Health Model Initiative (IHMI) is working to improve the ability to share and use data to improve patient health outcomes. IHMI uses the best available science to define and model meaningful and clinically-valid data elements, including patient function, state, goals and SDH, in high-burden disease areas. IHMI features three components:

- A digital community for hosting collaborative groups reflective of IHMI’s current focus and work;
- A physician-led validation process to review clinical applicability; and
- A technology-agnostic clinical information model for organizing and exchanging data: The Integrated Health Model (IHM).

IHMI is a platform for developing data portability solutions. Data liquidity, also known as semantic interoperability, is the ability to exchange usable data. A requirement for liquidity is portability, which occurs when the exchanged data are defined in a semantically-harmonized, consistent manner down to the level of computability for automated information exchange. IHMI works by accepting clinical content submissions, which it evaluates for inclusion in the IHM. If a submission is accepted a clinical validation process is run to convert the submission into a business requirements specification. This specification is then used to model the data structures needed to create computable, structural representations of clinically meaningful data elements that can be used by any electronic system to capture, exchange, store, and analyze health data. The development and use of the IHM is anticipated to enable better outcomes analysis, empowering clinicians and patients with data that can be trusted for clinical decision making. IHMI aims to model patient health state, functional status, SDH and patient health goals across high-burden diseases where needed data in these domains are not well-represented in current available data standards. Improved ability to capture these data in a clinically valid, structured, standardized manner is anticipated to have many benefits, including increased success in the execution of value-based payment models.

IHMI as a benefit to provider organizations

The development in the IHM of clinically-valid information models for high-priority use cases e.g., the capture and use of SDH data to identify patients with social risk factors is expected to improve the quality and usability of health data. Increased availability and use of those data has the potential to improve health outcomes by reducing clinical variation in data from the extremely varied sources of SDH data.

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Reduction in the incidence of false signals and other interpretive errors may be a benefit to operational efficiency, helping clinicians and providers to perform more effective risk prediction, targeting patients who are truly at risk with the right care and resources they need.

Care plan effectiveness may benefit from the enablement of feedback loops between patients monitoring their health at home and the clinicians providing their care. For hypertension and other similar disease states, office visits may be better utilized reducing cost to patients and provider organizations. Facile incorporation of SDH data at the point of care is expected to improve shared decision making and health outcomes for patients with social risk factors.

How IHMI is working to help provider organization realize these benefits

IHMI has released Self-Measured Blood Pressure Monitoring, version 1.0 (SMBP1), modeling patient health state in hypertension. Future releases are expected to expand IHM’s coverage of this disease state with the inclusion of an initial set of SDH that are relevant in hypertension but also to diabetes and asthma.

In high risk populations, access to resources is a common and significant SDH factor. Remote monitoring together with education about how to use remote monitoring can help address the issue of access to health care resources. Remote monitoring then can range from SMBP for patients who are assessed to be good candidates to using kiosk devices such as what can be found in their local pharmacies, to mobile clinics that bring services to the county/community.

IHMI is modeling SDH data beginning with five-digit zip code with optional plus four as a proxy for geographic location, which has been correlated with socioeconomic and sociodemographic status, along with dual eligible status. The initiative is working within its collaborative community to identify additional SDH factors for inclusion in future IHMI releases, depending on market demand. The AMA and its IHMI look forward to its efforts in this domain being further informed by the ASPE’s report.

Conclusion

The AMA appreciates the opportunity to provide our comments on this important issue. If you should have any questions regarding this letter, please feel free to contact Koryn Rubin, Assistant Director for Federal Affairs, at koryn.rubin@ama-assn.org or 202-789-7408.

Sincerely,

James L. Madara, MD