Professional Perspective

Value-Based Advancement of Health Equity

Stephanie Gross, Amy Joseph, and Sandi Krul, Hooper Lundy & Bookman

Bloomberg Law
Value-Based Advancement of Health Equity

Contributed by Stephanie Gross, Amy Joseph, and Sandi Krul, Hooper Lundy & Bookman

Martin Luther King, Jr. declared in 1966 that “Of all the forms of inequality, injustice in health is the most shocking and the most inhuman because it often results in physical death.” More than 50 years later, experts continue to report that vast health inequities persist among racial, ethnic, and socioeconomic groups, in large part, because of the different conditions into which persons are born, live, learn, work, play, worship, and age—known as social determinants of health (SDOH), as well as implicit biases.


Fortunately these disparities have prompted a renewed focus and determination on addressing implicit bias and SDOH to advance health equity—for every person to have the opportunity to “attain his or her full health potential” and no one “disadvantaged from achieving this potential because of social position or other socially determined circumstances.” The Biden administration has also formed a Covid-19 Health Equity Task Force to provide recommendations for addressing health inequities caused by the pandemic and for preventing future inequities.

At the same time, there is recognition that it will be difficult to effectively target barriers to health equity unless regulatory barriers are also reformed. This article focuses on recent developments and clarifications focused on overcoming those barriers to support providers seeking to address SDOH as a critical component of patient care:

- New federal anti-kickback statute safe harbor for patient engagement tools and supports
- Medicare Advantage supplemental benefits expansion
- Confirmation by the U.S. Department of Health and Human Services Office for Civil Rights (HHS-OCR) regarding sharing of records with social agencies or other third parties for better coordination of care
- Other federal and state programs designed to transform health-care delivery systems and reduce disparities

Value-Based Anti-Kickback Statute Safe Harbor

The federal anti-kickback statute is a criminal law that prohibits knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving items or services reimbursable by federal health-care programs. The law's breadth and potential consequences for violations produce a chilling effect on innovative payment models and efforts to address SDOH.

In response, HHS introduced sweeping new changes to federal anti-kickback statute safe harbors as part of its Regulatory Sprint to Coordinated Care. These changes, effective Jan. 19, 2021, include three broad new safe harbors for “value-based arrangements.” 42 U.S.C. § 1320a-7b(bb); 42 C.F.R. § 1001.952(ee)-(gg); 85 Fed. Reg. 77684 (Dec. 2, 2020). New, similar value-based exceptions under the federal physician self-referral law, also known as the Stark law, took effect on the same date. 42 C.F.R. 411.357(aa).

At a high level, these new safe harbors protect arrangements involving two or more participants who collaborate to engage in activities related to a target patient population for a value-based purpose—e.g., activities to promote care coordination and management, quality improvement, or reduction in payor cost, without reducing quality of care. 42 C.F.R. § 1001.952(ee). These safe harbors vary in scope and number of requirements based on the level of risk undertaken by the enterprise, ranging from full risk—where the enterprise is financially responsible on a prospective basis for all items and services covered by a payor—to no risk.

A significant benefit of participation in a value-based arrangement is the ability to use the new “patient engagement and support” safe harbor for patients in a target patient population. 42 C.F.R. § 1001.952(hh). This safe harbor, available to participants of value-based arrangements only, protects in-kind remuneration to a patient if connected to a patient’s care, and if it advances one or more of the following goals: patient adherence to a treatment regimen, drug regimen, or follow
up care plan; prevention or management of a disease or condition; or patient safety. The safe harbor protects remuneration with a value of up to $500 annually, with an annual CPI-U adjustment.

This new patient engagement safe harbor is significant for a few reasons. First, although under certain circumstances providers currently can rely on various exceptions to the beneficiary inducement provision of the civil monetary penalties law for provision of free or discounted items or services (the Beneficiary Inducements CMP), such as the so-called “promoting access to care” exception, there is no safe harbor under the federal anti-kickback statute to protect all such arrangements. 42 U.S.C. § 1320a-7a(a)(5); 42 U.S.C. § 1320a-7a(i)(6); 42 U.S.C. § 1003.110.

Conversely, if an arrangement meets a safe harbor to the federal anti-kickback statute, it is also not subject to the Beneficiary Inducements CMP. 42 U.S.C. § 1320a-7a(i)(6)(B); 42 U.S.C. § 1003.110. Although a provider may determine an arrangement is low-risk under the federal anti-kickback statute if meeting a Beneficiary Inducements CMP exception, there is not the same certainty as when a safe harbor applies. Second, the new safe harbor covers a broader range of items and services than what may be covered by a Beneficiary Inducements CMP exception.

A key theme in the commentary to this new safe harbor is the recognition of the importance of addressing SDOH. 85 Fed. Reg. at 77794-95. The HHS Office of Inspector General (OIG) cites to the preamble of its proposed rule, regarding the “existence of substantial evidence that ‘unmet social needs’ related to social determinants of health such as transportation, nutrition, and safe housing play a critical role in health outcome and expenditures, two key policy goals of this rulemaking.” The OIG expressly declined to list in the regulations examples of patient tools and supports that could be provided to address SDOH, to avoid inadvertently stifling innovation. However, a number of examples provided in the commentary illustrate broad support for addressing SDOH. Some of these examples include:

- Provision of in-kind transportation—e.g., transit vouchers, rideshares
- Home modifications such as grab bars, air filters, or purifiers
- Temporary housing for an individual experiencing homelessness following discharge
- Providing broadband access to a patient to enable remote patient monitoring
- Grocery or meal delivery services, nutrition education
- Exercise programs or fitness equipment
- Vehicle modifications
- Incentives as part of addiction recovery or mental health programs
- Supports related to interpersonal violence

**Medicare Advantage Plan Benefits**

Even though services like transportation, housing, and meals can have an immediate impact on an individual’s health, these services are not covered by Medicare. As such, CMS will not reimburse a provider directly for providing these services to a traditional Medicare beneficiary. The new safe harbors discussed above create flexibility for providers and other service organizations to collaborate to provide these services to Medicare beneficiaries without running afoul of the anti-kickback statutes.

However, Medicare Advantage organizations face an additional regulatory hurdle to offering these services to their enrollees: historically, any additional benefits Medicare Advantage organizations offered enrollees beyond Medicare’s traditional services were required to be “primarily health related.” This requirement was interpreted narrowly, and stood in the way of Medicare Advantage organizations seeking to offer benefits that indirectly impacted enrollees’ health by addressing social needs. With two recent changes, however, Medicare Advantage organizations now enjoy greater flexibility in this area.

First, in a 2018 guidance document, CMS expanded its interpretation of services that are considered “primarily health related” to encompass a service that is “used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization.” CMS pointed to in-home support services and transportation to obtain health-care services as examples of
services that would be considered “primarily health related” under this new definition, and can thus be covered by Medicare Advantage plans.

Second, a recent change in law departed from the requirement that all Medicare Advantage services be “primarily health related” and established a flexible new category of benefits that can be offered to chronically ill enrollees. While the services need not be primarily health-related, they must “have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.” Pub. L. 115-123, § 50322 (amending 42 U.S.C. § 1395w-22(a)(3)) (2018); see also 42 C.F.R. § 422.102(f) (as finalized in the Medicare 2021 Medicare Advantage/Part D Final Rule, 85 Fed. Reg. 33796 (June 2, 2020). CMS refers to this new category of supplemental benefits as “Special Supplemental Benefits for the Chronically Ill (SSBCI).”

CMS provided the following examples of services that might be offered as SSBCI to address the needs of chronically ill enrollees:

Meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, indoor air quality and equipment and services, access to community or plan-sponsored programs and events to address enrollee social needs (such as non-fitness club memberships, community or social clubs, park passes, etc.), complementary therapies (offered alongside traditional medical treatment), services supporting self-direction, structural home modifications, and general supports for living (for example, plan-sponsored housing consultations and/or subsidies for rent or assisted living communities or subsidies for utilities such as gas, electric, and water). Medicare 2021 Medicare Advantage/Part D Final Rule, 85 Fed. Reg. at 33801. (Note that CMS has pointed to financial literacy classes, technology education, and language classes as examples of services supporting self-direction. 85 Fed. Reg. 9002, 9012 (February 18, 2020).

This list of services that may be offered as SSBCI overlaps in part with the items and services that can be offered under the patient engagement safe harbor described above. Notably, however, in the Medicare Advantage context, a Medicare Advantage organization can offer these services directly to enrollees as a plan benefit.

Sharing Patient Information

Pursuant to the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder (HIPAA), a covered entity may use and disclose protected health information, or PHI, for their own treatment, payment, and health-care operations. 45 C.F.R. § 164.506(c). In a Frequently Asked Question on the HHS website, which addresses the ability to refer a homeless patient with mental illness to a social services agency such as a housing provider, HHS stated:

Treatment includes the coordination or management of health care by a health care provider with a third party. Health care means care, services, or supplies related to the health of an individual. Thus, health care providers who believe that disclosures to certain social services entities are a necessary component of, or may help further, the individual’s health or mental health may disclose the minimum necessary PHI to such entities without the individual’s authorization. For example, a provider may disclose PHI about a patient needing mental health care supportive housing to a service agency that arranges such services for individuals.

Also as part of HHS’s Regulatory Sprint to Coordinated Care, HHS issued a proposed rule which would make changes to the HIPAA Privacy Rule. 86 Fed. Reg. 6446 (Jan. 21, 2021). One of the proposed changes is to include an express permission for covered entities to disclose PHI to social services agencies, community-based organizations, home and community-based service providers, and similar third parties that provide health-related services, to facilitate coordination of care and case management for individuals. See discussion at 86 Fed. Reg. 6476-77.

As an example, HHS provides that “food or sheltered housing needed to address health risks” can constitute health-related services, and a covered entity may disclose PHI to a third party providing such services for care coordination and care management purposes. As another example, HHS provides that “a covered entity could disclose the PHI of a senior individual experiencing chronic illness to a senior center attended by the individual to check on his or her health periodically, and to ask the senior center to give reminders about effective disease self-management.”
Importantly, HHS also states that it believes such disclosures are already generally permitted under the existing regulations regarding uses or disclosures for treatment purposes. The proposed express regulatory language is intended to provide “greater regulatory clarity,” and to “facilitate and encourage greater wraparound support and more targeted care for individuals, particularly where it would be difficult to obtain an individual’s authorization or consent in advance, because the individual cannot easily be contacted (e.g., when an individual is homeless).” While covered entities may determine it is a good practice to get a patient’s verbal or written consent where feasible before disclosing information to such third parties, the HHS guidance provides comfort by clarifying that it is not required.

Other Federal and State Developments

CMS has several initiatives aimed to make progress on health equity, including engaging in studies to understand and build awareness of health disparities, developing and disseminating solutions to achieve health equity, and providing guidance on implementing sustainable actions to achieve health equity. CMS guidance, issued in January 2021, encouraged state Medicaid directors to incorporate value-based strategies into their delivery models, noting that the adoption of value-based care arrangements provide opportunities to more effectively target SDOH as well as health disparities.

Indeed, we are seeing several important state actions to address SDOH. For example, California currently has two health equity bills under consideration. California’s AB 369 is aimed at folding street medicine into its state Medicaid program (Medi-Cal), which would allow for providers to treat patients outside the four walls of a facility or clinic as part of primary care and bill Medi-Cal for those services (presently not billable under Medi-Cal).

The second, AB 1038, would, among other things, establish the California Health Equity Program—a competitive grant program administered by the Office of Health Equity to community-based nonprofit organizations, community clinics, local health departments, and tribal organizations to take actions related to health equity—establish the California Health Equity Fund to fund the grant program, and establish the California Health Equity Fund Oversight and Accountability Committee to monitor the distribution, implementation, and impact of local and regional grants funded by the California Health Equity Fund.

In 2020, Massachusetts formed a Covid-19 Health Equity Advisory Group to advise its Department of Public Health on the needs of communities and populations disproportionately impacted by the pandemic, including a subcommittee focused specifically on SDOH. And on Jan. 1, 2021, Massachusetts passed legislation which, among many other things, requires the Massachusetts Health Policy Commission (HPC) to conduct an analysis and issue a report on the effects of the pandemic on the health-care delivery system.

In doing so, the HPC was directed to seek particular input from “a range of diverse stakeholders including those disproportionately impacted by Covid-19 or social determinants of health.” The HPC report is required to include “an assessment and detailed description of the essential components of a robust health-care system and the distribution of services and resources necessary to deliver high-quality care, from birth to death, to all residents in the commonwealth, including, but not limited to, the appropriate level of personal protective equipment at health-care facilities to ensure the health of facility personnel and patients, and eliminate health care disparities due to economic, geographic, racial or other factors.” Session Law, Acts of 2020 Chapter 260; see also initial interim report released in April 2021.

These are just a few examples of the varied state programs designed to transform health-care delivery systems to improve health and control costs, through a specific focus on addressing SDOH to reduce health disparities. The National Academy for State Health Policy showcases many of these state SDOH programs on its website.

Conclusion

Health-care providers cannot solve the health equity problem alone. Even with the highest quality health care, true gains will only be made when we also address the SDOH, bias, and other issues that contribute to the health inequities. Fortunately, the regulatory changes and clarifications described in this article provide important tools and supports for health-care providers to partner with other providers and social services organizations in a true continuum of care targeted at promoting health equity.