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Social determinants of health

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The concepts behind social determinants of health (SDOH) have been with us for many years. The Commission on Social Determinants of Health was established by the World Health Organization in 2005 to consider social conditions that affect a society's poor health and health inequalities. The commission's initial work has been further developed over the years, resulting in several formats, including the current one used by the Office of Disease Prevention and Health Promotion (ODPHP) under the U.S. Department of Health & Human Services. The department establishes public health objectives every 10 years, with the current plan covering the 2020–2030 period.[1] The department's objectives include SDOH, leading health indicators, and overall health and well-being measures.

SDOH basics

ODPHP defines SDOH as "conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."[2] It groups the determinants into five domains that play a role in improving a community's health outcomes (Table 1). Each domain has specific goals and objectives established by ODPHP. Even though they are separate areas, they are interconnected, and improvements in one area can have a positive impact on other domains.

Domain	Economic stability	Education access and quality	Healthcare access and quality	Neighborhood and built environment	Social and community context
Goal	Create steady incomes that allow people to meet their healthcare needs.	Increase educational opportunities and help children and adolescents do well in school.	Increase access to comprehensive, high-quality healthcare services.	Create neighborhoods and environments that promote health and safety.	Increase social and community support.

Objectives	• Increase employment • Affordable housing • Reduce food insecurity and hunger	• Increase proficiency in math and reading • Provide preventive mental healthcare services in school • Participation in high-quality early education	• Improve health literacy • Increase healthcare insurance coverage • Access to medical services when needed	• Reduce violent crime • Improve air and water quality • Transportation systems to promote walking and biking	• Reduce bullying • Improve availability of someone to discuss concerns with • Reduce incarceration rates for parents and guardians

Table 1: The five SDOH domains that affect a community's health outcome improvement.

Economic stability can result in improved nutrition and affordable housing. This in turn can promote better performance in school for children, address mental health concerns related to homelessness, and decrease food insecurity for adults and families. Some healthcare organizations are faced with challenges related to treating individuals without adequate housing. This can range from the individual who is homeless to someone who lacks a consistent address to provide care. Addressing concerns in this domain can have far-reaching improvements in many of the other domains.

Improvements in a community's physical environment and social support affect both health outcomes and the use of healthcare services. Respiratory illnesses, such as asthma and other pulmonary diseases, can be difficult to manage in communities with poor air quality, resulting in increased readmissions and additional clinic visits.[3] Suicide is one of the leading causes of death in the United States, with rates being higher in rural counties than in metropolitan areas.[4] Actions to reduce bullying in schools, improving a community's social support network, and expanding access to mental health services can reduce the number of suicides.

ODPHP is not the only federal entity that has a role in this area. Other agencies such as the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality participate in research related to SDOH. The Centers for Medicare & Medicaid Services (CMS) is also taking action in this area.

SDOH and CMS

On January 7, guidance was issued to state health officials outlining opportunities in the Medicaid and Children's Health Insurance Program (CHIP) programs to address SDOH.[5] These programs provide support to low-income individuals, and they may design services to address specific healthcare needs as long as certain federal requirements are met. CMS recognized the Medicaid and CHIP programs are well positioned to directly affect SDOH with their wide range of home and community services. The letter provided specific recommendations to address actions to promote community versus institutional living, connecting individuals with available resources, education for children with disabilities, and transportation for needed items such as food. By designing programs to improve the health outcomes for beneficiaries, CMS expects to lower overall healthcare

costs in the Medicaid and CHIP programs.

Establishing and monitoring quality measures provides CMS with a method to evaluate progress in improving health outcomes related to SDOH. Measures have been developed for a wide variety of care settings that affect all levels of the healthcare continuum. Just a few programs include hospitals, ambulatory surgery centers, imaging facilities, clinics, and physician services. These measures provide data to evaluate clinical care processes, specific health outcomes, and patient reported outcomes. Over time, measures can be developed and refined to promote and enable healthy living for CMS beneficiaries.

Conditions of participation are another method available to CMS to support improvements in SDOH. The discharge planning requirements for hospitals were revised in 2020 to improve the transition from acute to post-acute services.[6] Hospitals are required to identify and evaluate patients at risk for adverse health outcomes following discharge if adequate discharge planning is not performed. The evaluation should be comprehensive and consider nonhealth needs as well as medical needs. Hospital case management teams may have already been active in this area prior to the revision. For example, a request may have been made for a physician to add social work services to home health discharge orders to address a patient's report of food insecurity. Conditions of participation revisions have established the expectation that the process is consistent and well documented in the patient's medical record for review by a state surveyor.

There are many paths open to CMS to affect SDOH. Revisions in the quality assurance and performance improvement (QAPI) requirements could be used in the future to drive improvements in health outcomes. QAPI combines the traditional retrospective approach of quality assurance programs with continuous process improvement. Requiring clinical programs to include SDOH indicators specific to their services would support CMS's focus to improve the quality of care provided to beneficiaries. Other changes could be made that require Medicare and Medicaid programs to develop and analyze SDOH data. These are only a few examples of possible changes, and SDOH are expected to be an active area of future revisions for healthcare programs.

Anti-Kickback Statute

Addressing SDOH aligns with many organizations' mission statements to serve their communities and patients. Management, department groups, and individual team members may be interested in developing services that specifically affect SDOH. Unfortunately, some of these actions may have potentially unintended compliance consequences. The Anti-Kickback Statute (AKS) prohibits the solicitation, offering, or payment for patient referrals that are payable under a federal healthcare program.[7] The definition of renumeration is quite broad and can cover a wide range of potential inducements for prohibited actions.

The Office of Inspector General (OIG) advisory opinions are a resource for compliance professionals considering potential risks in this area.[8] The opinions provide a summary of how the AKS was applied to a specific request from an individual or organization. The OIG website cautions that the opinions can only legally be relied on by the requester, but they can provide helpful examples for compliance professionals to increase their knowledge and as examples for education purposes.

As an illustration, OIG Advisory Opinion No. 20-08 responds to a proposal to offer gift cards to incentivize certain pediatric patients to attend rescheduled preventive and early intervention care appointments.[9] This proposed program clearly falls within a potential AKS concern. The requester has determined that, on average, 30% of its pediatric patients have missed at least one appointment. Pediatric patients would be offered a $20 gift card in return for scheduling and completing an appointment. The gift card serves as an inducement to complete an appointment with the entity. At the same time, the completion of pediatric visits for both preventive and treatment services fit well within an organization's desire to improve the health outcomes for its patients.

The advisory opinion's analysis of the law and the proposed arrangement can serve as a resource for questions to ask when consulted about a possible program or ideas to consider when discussing the structure of a program with others. The legal analysis portion of the opinion includes a summary of the AKS and the definition of renumeration. It discusses how the statute has been interpreted, notes the OIG's position on incentives that are only nominal in value, and provides footnotes to locate references. The analysis of the proposed arrangement highlights the reasons the OIG determined it would not impose sanctions. It concluded that potential patients already had an established relationship with the organization, the increased cost would reflect appropriate use, the program would not be advertised, and the arrangement was reasonably tailored to accomplish the goal to improve the attendance rate for appointments.

On December 2, 2020, a final rule was published in the *Federal Register* to amend the safe harbors to the AKS.[10] The executive summary of the final rule includes a brief discussion of the application of the AKS that can serve as another resource for compliance professionals. It notes that when parties are exchanging nothing of value, or the arrangement does not involve federal healthcare program patients, the AKS is not implicated. Structuring arrangements to fit an existing safe harbor is another method to not implicate the AKS. The summary goes on to say arrangements are not necessarily unlawful when they do not fit in a safe harbor; OIG will analyze the compliance of the structure based on the facts and the intent of the parties.

New programs

When approached regarding a new program, it is important to understand how the need for the program was identified and what goals the organization wants to achieve. Programs designed to meet a well-documented need to improve care coordination will be viewed in a different light than those with a goal to increase patient referrals.

Requesting and subsequently maintaining a complete description of the program can serve many purposes. The specific details of the proposed arrangement will assist in determining the potential implication of the AKS and establish clear requirements for the implementation of the program. Over time, the organization may experience changes in management and employees that can result in revisions to the arrangement with unintended consequences. A comprehensive description can also assist in establishing structural safeguards to prevent future concerns and program components that would benefit from a periodic review.

Using the proposed arrangement discussed in the OIG's advisory opinion as an illustration, a compliance professional may determine the highest-risk areas are the dollar amounts of the gift cards and confirmation that the needed visit was completed prior to receipt of the gift card. In response, the decision is made to have the finance department issue the gift cards to the requesting department to ensure the value of the cards does not change over time. A report is developed for the compliance team by the information technology department and the requesting department to identify the missed visits and the visits when the gift card is issued.

Managing potential risks

Communication is an important first step in managing risks related to programs to address SDOH. Establish a plan to inform leaders and appropriate staff members about the compliance risks associated with this type of program. The goal is not to be the department that puts up barriers to such ideas. Instead, sharing examples and ideas can illustrate how small changes in a proposed program might fit within a safe harbor or meet the OIG's definition of nominal value. This is also the time to discuss why it is important to understand the rationale for the program and the need for any available data to support the program.

It is very likely we will continue to see revisions related to safe harbors and additional guidance in this area from the OIG. Coordination with the legal department is important to ensure the latest information is applied to the

review of any proposed or current programs. If the organization does not have a current process for both departments to review and approve these programs, consider implementing a formal process. Organizations that are too small to have a legal department may want to arrange a relationship with a knowledgeable legal resource for future needs.

Risk mitigation steps should be built in both at the organizational level and the individual program level. It is important for the compliance department to know where these programs and activities are occurring in an organization. Actions to address SDOH may not necessarily be a formal program in a department. For example, providing free baby products to clinic patients may be well intentioned but could possibly have unintended compliance concerns. Current compliance communication forums, such as annual training and periodic alerts, can be used to share examples with employees and provide contact information to discuss any questions. If existing programs or activities are identified, they should undergo a similar process to new programs to include documentation to support the need for the service, a description of the activities, and any needed safeguards to limit compliance risks.

Regulatory changes and guidance related to SDOH are expected in the future, and organizations need a robust method to track revisions in a timely manner. Periodically review how the organization monitors these changes as part of risk assessments. If knowledge of changes is not as timely as possible, take the time to find out why and work with leadership to address the issue.

When auditing programs or changes are made to meet revised regulatory requirements, perform the audit as if you are an outside entity. It certainly can take less time to access the electronic health system to confirm case management is completing a screening tool. Unfortunately, this method may not tell you the document is not included in the medical record that is provided to the state surveyor.

Conclusion

The goal for the compliance team is to increase awareness regarding compliance risks related to SDOH and assist leaders in implementing programs based upon appropriate organizational goals. Be alert to the potential risk that a program is actually designed to drive referrals, with improved health outcomes serving only as a secondary goal. It is important to have a thorough understanding of why the program is needed and the facts behind the decision to proceed with the program.

Takeaways

- Well-intentioned programs to address social determinants of health may have unintended compliance consequences.
- Maintain documentation to support why the program was needed and the expected outcomes from the program.
- Use examples during training sessions to increase organizational knowledge related to these programs.
- Coordination with legal resources can help identify legal risks and any safe harbors for program development.
- Have a thorough understanding of a program to confirm improved health outcomes is not serving as a secondary goal to increasing referrals.

1 "Social Determinants of Health," Healthy People 2030, ODPHP, accessed March 16, 2021, http://bit.ly/3tmQjOa.

2 "Social Determinants of Health," Healthy People 2030, ODPHP.
3 Xu-Qin Jiang, Xiao-Dong Mei, and Di Feng, "Air pollution and chronic airway diseases: what should people know and do?" *Journal of Thoracic Disease* 8, no. 1 (January 2016), http://bit.ly/30PjAou.
4 Asha Z. Ivey-Stephenson et al., "Suicide Trends Among and Within Urbanization Levels by Sex, Race/Ethnicity, Age Group, and Mechanism of Death — United States, 2001–2015," *Surveillance Summaries* 66, no. 18 (October 6, 2017), *Morbidity and Mortality Weekly Report,* http://bit.ly/3qYxAa6.
5 CMS, "Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH)," State Health Official letter #21-001, January 7, 2021, https://bit.ly/3141H5H.
6 42 C.F.R. § 482.43 .
7 42 U.S.C. § 1320a-7b .
8 "Advisory Opinions," Office of Inspector General, U. S. Department of Health & Human Services, accessed March 16, 2021, http://bit.ly/3vAXuEz.
9 Robert K. DeConti, "Re: OIG Advisory Opinion No. 20-08," Office of Inspector General, U. S. Department of Health & Human Services, December 30, 2020, https://bit.ly/3vxOwI6.
10 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (December 2, 2020) .