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FINDING AN OASIS IN THE FOOD DESERT:

LEGAL ISSUES IN ONE SOCIAL DETERMINANT OF HEALTH

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I. Introduction.

The cost of health care in the United States continues to increase. Between 1999 and 2019, health care spending as a share of GDP rose by 4.5% from 13.2% up to 17.7%.[1] The Centers for Medicare and Medicaid Services (CMS) estimated that for the year 2020, health expenditures accounted for approximately 19.7% of GDP, for a total of $4.1 *trillion*, amounting to $12,530 per person.[2] While the total number of uninsured, non-elderly Americans dropped from 48 million in 2010 to 30 million in the first half of 2020, the U.S. population as a whole has grown older. Between 2000 and 2020, the proportion of the American population aged 65 and older increase by 60% and is projected to increase by another 44% between 2020 and 2040.[3] As the cost of, and need for, health care in the United States continues to increase, regulators, health care providers, and patients alike all look for ways to reduce costs and improve outcomes.

Social determinants of health (SDOH) have been recognized as a major influence upon and shaper of health care conditions, outcomes, and expenses. Social determinants of health include factors such as housing, food, and nutrition. Policies and programs designed to improve SDOH can help improve people's overall health, acting as a kind of preventive medicine. As a result, the federal government, and state governments alike are developing new ways to address SDOH for patients. For example, on January 7, 2021, as one of its first acts in office, the Biden administration released a guidance letter to state health officials responsible for the operation of state Medicaid programs, providing instructions on how states could take advantage of various waiver authorities within Medicaid to implement programs to address SDOH.[4]

Health care providers, including physicians and physician practices, may want to avail themselves of these new programs. With that in mind, this article will provide a general overview of SDOH, explaining what they are and how they influence health care. It will explore federal efforts to address SDOH, especially those relating to food, nutrition, diet, and health conditions tied to these factors, through a variety of programs including

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[1] "Health Care Costs 101: Spending Growth Outpaces Economy," California Health Care Foundation, June, 2021, available at, https://www.chcf.org/publication/2021-edition-health-care-costs-101/#:~:text=Health%20Care%20Costs%20101%3A%20US,and%20consumer%20prices%20(1.8%25).

[2] National Health Expenditure Accounts, available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

[3] "Cost of Caring," American Hospital Association, October, 2021, available at, https://www.aha.org/guidesreports/2021-10-25-cost-caring.

[4] Costello, Anne Marie, "Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH)," SHO# 21-001, January 7, 2021.

current traditional Medicare programs, changes to the Medicare Advantage program, and changes resulting from the Affordable Care Act and other regulatory measures. The article will also address Medicaid programs and state efforts to tackle SDOH through Medicaid's waiver system. All of this is with a light focus on physicians and their practices. Finally, it will explore legal concerns that may arise in relation to these varying efforts.

II. Social Determinants of Health Generally

Although currently somewhat of a buzzword, the concept of SDOH has existed for many years. The term appears at least as far back as 1998.[5] Social determinants of health, sometimes also referred to as "drivers of health," generally refer to conditions in people's lives that influence their health and life quality.[6] Definitions of the term vary. For example, the Office of Disease Prevention and Health Promotion within the Department of Health and Human Services defines SDOH to mean: "The 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."[7]

The World Health Organization takes a somewhat more expansive view, defining SDOH to mean:

> "*Non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems. [SDOH] have an important influence on health inequities – the unfair and avoidable differences in health status seen within and between countries. In countries at all levels of income, health and illness follow a social gradient: the lower the socioeconomic position, the worse the health.*"[8]

The bottom line, however, is that social determinants of health are non-medical factors which influence the health of individuals and which can themselves result in medical outcomes, both positive and negative.

As suggested by both definitions, social determinants of health can include a broad range of circumstances. These include economic stability, neighborhood physical

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[5] "Social Determinants of Health – The Solid Facts," World Health Organization, 1998, available at https://apps.who.int/iris/handle/10665/108082.

[6] "Bridging Health and Health Care," Bipartisan Policy Center, September, 2021, p.9.

[7] Office of Disease Prevention and Health Promotion, Healthy People 2030, at https://health.gov/healthypeople/objectives-and-data/social-determinants-health.

[8] World Health Organization definition of "Social Determinants of Health," available at https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.

environment, education, community and social context, housing and housing stability, health care access and quality, and food and access to food. They can affect health outcomes such as morbidity, mortality, life expectancy, functional limitations, and, of course, health care expenditures.[9]

The impacts of SDOH are widespread and significant. The Centers for Disease Control's National Center for Chronic Disease Prevention and Health Promotion has estimated that 6 out of 10 Americans have a chronic disease, and 4 out of 10 have two or more. These diseases include Alzheimer's, stroke, cancer, chronic lung disease, heart disease, chronic kidney diseases, and diabetes. Diseases such as heart disease, cancer, and diabetes have been described as the leading causes of death or disability in the United States.[10] Related to this, SDOH such as housing, food access, and nutrition insecurity have been estimated to be at the root of up to 80% of health outcomes.[11]

Diet and nutrition, especially access to nutritious food, are especially influential in terms of health outcomes and health care costs, with diet itself having been described as the leading driver of death and disability in the United States.[12] For example, approximately 45% of cardiometabolic deaths in 2012 were found to be attributable to poor diets with high sodium and high processed meats intake, low intake of seafood omega-3 fats, and low intake of nuts, seeds, and vegetables.[13]

Chronic health conditions such as diabetes, hypertension, and obesity also create significant cost burdens on the American health care system. According to the American Diabetes Association, 1 in 10 Americans have diabetes; and $1 out of every $4 spent in the United States health care system is spent on diabetes care. This amounts to a total of $297

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[9] See, World Health Organization definition of "Social Determinants of Health," available at https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1; Artiga, Samantha and Elizabeth Hinton, "Beyond Health Care: the Role of Social Determinants in Promoting Health and Health Equity," Kaiser Family Foundation, Issue Brief, May 10, 2018, available at https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/; Office of Disease Prevention and Health Promotion, Healthy People 2030, at https://health.gov/healthypeople/objectives-and-data/social-determinants-health.

[10] "About Chronic Diseases," National Center for Chronic Disease Prevention and Health Promotion, available at, https://www.cdc.gov/chronicdisease/about/index.htm.

[11] "Addressing Social Factors That Affect Health: Emerging Trends and Leading Edge Practices in Medicaid," State Health & Value Strategies, April, 2019, available at, https://www.manatt.com/Manatt/media/Documents/Articles/Social-Factors-That-Affect-Health_Final.pdf.

[12] Mozaffarian, Dariush, M.D., "Want to fix America's Health Care? First, focus on food," The Conversation, September 12, 2017, available at, https://theconversation.com/want-to-fix-americas-health-care-first-focus-on-food-81307.

[13] Micha, R.D., Ph.D., Renata, and Jose L. Penalvo, Ph.D., et al., "Association Between Dietary Factors and Mortality from Heart Disease, Stroke, and Type 2 Diabetes in the United States," JAMA, March 7, 2017, Vol. 317, No. 9, p. 913, available at, https://jamanetwork.com/journals/jama/fullarticle/2608221.

billion spent each year on direct medical costs, and an additional $90 billion spent on reduced productivity, all attributable to diabetes. Total expenditures on diabetes in 2017 were estimated to be $327.2 billion. Between 48% and 64% of lifetime medical costs for a person with diabetes was attributable to complications relating to diabetes, such as stroke or heart disease, and people suffering from diabetes faced average medical expenditures of roughly $16,750, with more than half of that amount attributable to diabetes.[14] The American Medical Association has further estimated the costs of pre-diabetes in a study that found newly diagnosed diabetes patients spent $8,941 more over a 5-year period than patients without a diabetes diagnosis.[15]

Hypertension is another chronic condition that imposes significant costs on the health care system, as well as on patients themselves, and results in negative outcomes for patients. The Centers for Disease Control (CDC) estimates that over 500,000 deaths per year can be attributed to hypertension as either a primary or contributing cause, and that almost half of all American adults have hypertension.[16] One study found that the estimated annual costs of hypertension in the United States for 2016 was approximately $79 billion.[17] Hypertensive patients pay almost $2000 more in health care expenditures per year and pay $1,557 more in annual prescription medication costs than non-hypertensive patients.[18]

Like hypertension and diabetes, obesity is a related condition that leads to greater expenses in the United States health care system. The CDC has estimated that among U.S. adults, the age-adjusted prevalence of obesity was 42.4% in 2017-2018.[19] By 2030, studies

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[14] Yang, Wenya, Timothy H. Dall, et al., "Economic Costs of Diabetes in U.S. in 2017," Diabetes Care, Vol. 41, May, 2018, p. 917, available at, See also, Cost-Effectiveness of Diabetes Interventions, National Center for Chronic Disease Prevention and Health Promotion, available at, https://www.cdc.gov/chronicdisease/programs-impact/pop/diabetes.htm. The total per-person expenditure attributable to diabetes was $9,600.

[15] Berg, Sara, M.S., "Higher costs of diabetes start at least 5 years before diagnosis," American Medical Association, April 16, 2021, available at, https://www.ama-assn.org/delivering-care/public-health/higher-costs-diabetes-start-least-5-years-diagnosis.

[16] "Cost Effectiveness of High Blood Pressure Interventions," National Center for Chronic Disease Prevention and Health Promotion, available at, https://www.cdc.gov/chronicdisease/programs-impact/pop/high-blood-pressure.htm.

[17] Dieleman, Ph.D., Joseph, Jackie Cao, M.S., et al., "U.S. Health Care Spending by Payer and Health Condition, 1996-2016," JAMA, March 3, 2020, Vol. 323 No. 9, p. 869, available at, https://jamanetwork.com/journals/jama/fullarticle/2762309.

[18] Kirkland, M.D., MSCR, Elizabeth B., Marc Heincelman, M.D., et al., "Trends in Healthcare Expenditures Among U.S. Adults with Hypertension: National Estimates, 2003-2014," Journal of the American Heart Association, 2018, p. 5, available at, https://www.ahajournals.org/doi/10.1161/JAHA.118.008731.

[19] Hales, M.D., Craig M., Margaret D. Carrol, M.S.P.H., et al., "Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017-2018," NCHS Data Brief, No. 360, February, 2020, p.1, available at, https://pubmed.ncbi.nlm.nih.gov/32487284/.

project that up to 50% of Americans could be obese.[20] In 2015, medical expenses related to obesity were estimated to have accounted for 7.91% of all expenses.[21] Between 2011 and 2016, U.S. annual expenditures on obesity were estimated to be $172.7 billion.[22] Individual annual excess expenditures were $1,861.[23]

Diabetes, hypertension, and obesity are each influenced by SDOH, such as "food insecurity." The United States Department of Agriculture (USDA) defines "food insecurity" to mean "the limited or uncertain availability of nutritionally adequate and safe foods, or limited or uncertain ability to acquire acceptable foods in socially acceptable ways."[24] The USDA classifies households as "food insecure" when they report three or more conditions that indicate food insecurity, such as "were unable to acquire adequate food for one or more household members because they had insufficient money and other resources for food."[25] In the United States in 2019, there were more than 35 million people, including 11 million children, who were classified as food-insecure.[26] In 2020, roughly 10.5% of households in the United States were food-insecure.[27]

Food insecurity can be driven by other factors, like income or accessibility. When income is a factor, the individual cannot afford nutritious food, even if such options exist. When accessibility is a factor, the individual may be able to afford nutritious food, but none is available, such as when the individual lives in a "food desert" or a "food swamp." The

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[20] Carlson, Eric R., L.M. Leyd, "The Impact of Obesity on United states Health Care Expenditures," Journal of Obesity & Weight Loss, 2018, available at, https://www.heraldopenaccess.us/openaccess/the-impact-of-obesity-on-united-states-health-care-expenditures.

[21] Carlson, Eric R., L.M. Leyd, "The Impact of Obesity on United states Health Care Expenditures," Journal of Obesity & Weight Loss, 2018, available at, https://www.heraldopenaccess.us/openaccess/the-impact-of-obesity-on-united-states-health-care-expenditures.

[22] Ward, Zachary J., Sara N. Bleich, et al., "Association of body mass index with health care expenditures in the United States by age and sex," PLoS ONE, March 24, 2021, p.6, available at, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247307#pone-0247307-t001.

[23] "Obesity Costs the Average U.S. Adult Almost $1,900 per Year: Study," U.S. News & World Report, March 24, 2021, available at, https://www.usnews.com/news/health-news/articles/2021-03-24/obesity-costs-the-average-us-adult-almost-1-900-per-year-study.

[24] USDA Economic Research Service, available at https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/measurement.aspx.

[25] USDA Economic Research Service, available at https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/measurement.aspx.

[26] "The Impact of the Coronavirus on Food Insecurity in 2020 & 2021," Feeding America, March, 2021, p. 2, available at, https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf.

[27] Coleman-Jensen, Alisha, and Matthew P. Rabbitt, et al., "Household Food Security in the United States in 2020," USDA Economic Research Service, Report No. 298, September, 2021, p. 4, available at, https://www.ers.usda.gov/publications/pub-details/?pubid=102075.

USDA defines a "food desert" as a low-income area where a substantial number of residents have limited access to a supermarket or local grocery store. That usually means that 40% or more of the residents in the area have low incomes, and live 1 mile or more away from a place to buy nutritious food.[28] A "food swamp," on the other hand, is defined as an area with a high concentration of stores that sell high-calorie fast foods, and where healthy alternatives are either not available or affordable, or where the less healthy ones are far more available and/or affordable.[29]

Food insecurity is estimated to contribute $52 billion in excess health care spending. Food-insecure individuals are more likely to have higher health care costs, not least because they will go to the emergency department and be admitted as hospital inpatients more often than food-secure individuals. Food-insecure Medicare beneficiaries spend $5,527 more on health care annually by comparison to food-secure beneficiaries.[30] One study estimated that annual health care expenditures for food-insecure adults are $1,834 higher than those of food-secure adults.[31] Among Medicare beneficiaries who are age 65 or older, or who have long-term disabilities, food insecurity is especially problematic. One out of ten enrollees who are 65 or older, and four out of ten enrollees who are younger than 65 experience food insecurity.[32]

III. Federal, State & Private Programs Impacting SDOH

Considering the prevalence and economic pressure on the American health care system resulting from SDOH generally, and diet, nutrition, and the SDOH that affect them more specifically, it should come as no surprise that payors and health care providers alike are taking notice and developing methods to address patient SDOH. These efforts are

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[28] Ploeg, Michele Ver, David Nulph, and Ryan Williams, "Mapping Food Deserts in the United States," December 1, 2011, available at, https://www.ers.usda.gov/amber-waves/2011/december/data-feature-mapping-food-deserts-in-the-us/.

[29] Cooksey-Stowers, Kristen, Marlene B. Schwartz, and Kelly D. Brownell, "Food Swamps Predict Obesity Rates Better than Food Deserts in the United States," International Journal of Environmental Research and Public Health, November 14, 2017, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5708005/#B5-ijerph-14-01366.

[30] Oronce, M.D., MPH, Carlos Irwin A., and Isomi M. Miyake-Lye, Ph.D., et al., "Interventions to Address Food Insecurity Among Adults in Canada and the US – A Systematic Review and Meta-analysis," JAMA Health Forum, August 6, 2021, p.1, available at, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2782895.

[31] Berkowitz, Seth A., and Sanjay Basu, et al., "State-Level and County-Level Estimates of Health Care Costs Associated with Food Insecurity," Preventing Chronic Disease, July, 2019, Available at: https://www.cdc.gov/pcd/issues/2019/18_0549.htm.

[32] Madden, Ph.D., Jeanne M., Prathwish S. Shetty, MSc., et al., "Risk Factors Associated with Food Insecurity in the Medicare Population," JAMA Internal Medicine, January, 2020, Vol. 180 No. 1, p. 144, available at, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2751945#:~:text=The%20pervasive%20food%20insecurity%20across,anxiety%20to%20be%20distinct%20factors.

occurring at the federal and state level, as well as with private payors. Physicians and physician practices that want to begin addressing SDOH will need to know their available options.

A. Healthy People 2030

The CDC's Healthy People 2030 initiative is part of a long-standing process by the CDC to promote health throughout the United States. Since 1980, the Surgeon General for the United States sets measurable objectives for the decade meant to measure the improvement of health. The Healthy People 2030 initiative is the most recent of these efforts, and was launched in August, 2020.[33] The program is chiefly focused on the collection of data, rather than reimbursement of providers or directly impacting health care delivery itself. Instead, the initiative sets out health goals to be met, and then measures whether the goals have been reached. There are 355 core objectives in the Healthy People 2030 initiative.[34] The objectives generally focus on a range of health conditions, behaviors, populations, settings, and systems. Objectives include reducing the proportion of people who had drug use disorder in the past year;[35] increasing the proportion of high school students who get enough sleep;[36] increasing the proportion of adults who use IT to track health care data or communicate with providers;[37] and, increasing the proportion of worksites that offer an employee physical activity program.[38]

Healthy People 2030 also focuses on SDOH, which are broken into specific categories: economic stability, neighborhood & built environment, education access & quality, social & community context, and health care access & quality. Each category of social determinant of health has specific, focused measures and objectives including specific targets for the measure. For example, within the economic stability category, the goals include: reducing household food insecurity and hunger to 6.0% of U.S. households;[39] and eliminating very low food security in children.[40] The full list includes others such as reducing the proportion of adolescents and young adults who aren't in school or working;

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[33] For general information on the Healthy People initiative, see, History of the Healthy People Initiative, at https://health.gov/our-work/national-health-initiatives/healthy-people/about-healthy-people/history-healthy-people.

[34] See, https://health.gov/healthypeople.

[35] https://health.gov/healthypeople/objectives-and-data/browse-objectives/addiction.

[36] https://health.gov/healthypeople/objectives-and-data/browse-objectives/sleep.

[37] https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-it.

[38] https://health.gov/healthypeople/objectives-and-data/browse-objectives/workplace.

[39] https://health.gov/healthypeople/objectives-and-data/browse-objectives/workplace.

[40] https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating/eliminate-very-low-food-security-children-nws-02.

increasing employment in working-age people; reducing the proportion of families that spend more than 30 percent of income on housing; and, reducing work-related injuries resulting in missed work days.[41] In addition to the target, the measures indicate the last reported outcome. For example, "reduce household food insecurity and hunger" was last measured at 11.5% in 2018.[42]

The initiative's reporting also includes recommendations for achieving the outcomes. For example, with respect to "reducing household food insecurity and hunger," the recommendation suggests providing additional benefits through nutritional assistance programs, increasing existing benefit amounts, and addressing unemployment.[43]

There are no penalties for health care providers (or, indeed, anyone) if the goals are not reached; and the CDC does not have either an enforcement mechanism to compel compliance, nor any kind of reimbursement or other incentive mechanism to promote it. Rather, the program is simply focused around measurement and reporting. Nevertheless, as part of the Department of Health and Human Services, the CDC's Healthy People 2030 initiative provides insight into the overall health goals of the federal government, and suggests what types of efforts the government is likely to focus on in the programs it employs that actually directly impact health care providers and patients alike, such as the Medicare program.

B. Medicare Part B

Traditional fee-for-service Medicare does not pay practitioners to manage SDOH themselves. In part, this is because Medicare can only cover "medically necessary" services, and does not and cannot cover those which are not medically. Although addressing SDOH might meet the definition of medical necessity in some cases, in others, it would not. For example, in Medicare Part B – the portion of Medicare that covers outpatient services provided by physicians, non-physician practitioners, testing companies, and other non-hospital/non-facility entities – is oriented around the treatment of individuals and management of their specific conditions. The program pays health care providers for the discrete services they perform towards these efforts. By contrast, SDOH often represent broader, systemic issues that are not always specific to the individual. Nevertheless, while this general rule holds in most cases, there are some services that physicians may offer which touch on issues pertaining to SDOH, such as those relating to diet and nutrition. Of course, there remain compliance risks involved in the provision of

[41] For the full list, see, https://health.gov/healthypeople/objectives-and-data/browse-objectives/economic-stability.

[42] See, https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating/reduce-household-food-insecurity-and-hunger-nws-01.

[43] See, https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating/reduce-household-food-insecurity-and-hunger-nws-01.

any of these services, such as compliance with enrollment requirements and fraud and abuse concerns, and these are addressed further below.

Part B coverage of diet- and nutrition-related services is most apparent in services designed to prevent and treat diabetes. Part B covered services include screening tests, hemoglobin A1c tests, the Medicare Diabetes Prevention Program (MDPP), diabetes self-management training (DSMT), and medical nutrition therapy (MNT). Medicare Part B also covers blood sugar monitors, blood sugar test strips, and lancets and lancet devices.

With respect to screening and hemoglobin A1c tests, Medicare currently pays for up to two diabetes screening tests per 12-month period. These tests include fasting glucose and other glucose tests as necessary.[44] Hemoglobin A1c testing is also covered, albeit with some limitations. For example, the test cannot be performed more than every 3 months for diabetic patients whose diabetes is controlled.[45] Medicare also covers glaucoma tests, with patients who have diabetes being considered high-risk for glaucoma.[46]

Other covered diabetes services under Medicare Part B include the Medicare Diabetes Prevention Program (MDPP), which is a once per lifetime program oriented around training and education to help prevent type-2 diabetes.[47] The program consists of weekly core sessions in a group setting over the course of 6 months, which is then followed by 6 further months of monthly core maintenance sessions. Within the sessions, attendees are provided with training on how to make durable behavioral changes to their diet and exercise, tips on how to exercise more often, weight control strategies, work with a coach to help maintain motivation, and support from other individuals with similar goals within the group setting.

The MDPP also has an Expanded Model, which is provided by diabetic coaches who can be trained community health professionals, including physicians. To become a diabetic coach, the professional must meet certain eligibility requirements governed by regulation. For example, the coach must not currently be under a Medicare billing privilege revocation or re-enrollment bar, may not have been excluded from other federal health care programs, or have in the previous 10 years one of several types of state or federal felony convictions such as crimes against persons (e.g., rape, murder, assault, etc.), financial crimes (e.g., extortion, embezzlement, etc.), or felonies that place Medicare or its beneficiaries at immediate risk (e.g., a malpractice suit that could result in being convicted).[48] Coverage for

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[44] See, Medicare National Coverage Determinations Manual, Part 3, Ch. 1, § 190.20.

[45] See, Medicare National Coverage Determinations Manual, Part 3, Ch. 1, § 190.21.

[46] See, https://www.medicare.gov/coverage/glaucoma-tests.

[47] The program is covered under 42 CFR § 410.79. For additional information, see, "Medicare Diabetes Prevention & Diabetes Self-Management Training," Medlearn Matters Network, MLN909381, March, 2021.

[48] The above is not the full list of criteria. For the full list, see 42 CFR § 424.205(e).

MDPP services are paid on a per-session basis. The 1st, 4th, and 9th classes are each paid for during the first 6-months. In the second 6-month period, during core maintenance, payment varies based on the patient's weight loss goals, with greater reimbursement being tied to greater weight loss achievements.[49]

Medicare Part B also covers Medical Nutrition Therapy (MNT). The MNT service includes educational programs provided by a registered dietitian or nutritionist that are designed to train individuals to manage their nutritional intake when they have diabetes or renal disease.[50] For the first year, MNT is limited to three hours of therapy, and is reduced to two hours of therapy in subsequent years. However, the patient's treating physician may order additional hours beyond these limits if the physician determines a change in diagnosis, medical condition, or treatment regimen that requires a change in MNT.[51] The time spent may also depend on the other services for which the patient is eligible. For example, if the patient is also eligible for Diabetes Self-Management Training (DSMT, discussed further below), Medicare only covers a single pool of hours applicable to both programs. In other words, if DSMT covers ten hours of training, and MNT covers three hours, the beneficiary could receive the full three hours of MNT, and then only have seven hours for DSMT remaining.[52] When the beneficiary is eligible for MNT and follow-up DSMT, coverage is limited even further to the maximum number of hours available for MNT alone.[53]

For DSMT, Medicare covers the provision of preventive services meant to teach patients to manage their diabetes and prevent further complications.[54] These services require that a physician or qualified non-physician practitioner develop a plan of care based on their assessment of the patient. The plan must specify the content of the DSMT, the number of sessions to be provided, the frequency, and the duration of the training.[55] There are two types of training: initial training and follow-up training. Initial training is limited to ten hours total over a continuous 12-month period, with nine of the hours provided in a group setting of between 2 and 20 individuals, although the individuals at the group sessions do not all need to be Medicare beneficiaries themselves. Each session must last for at least 30 minutes. Initial training may also include one hour of individual training

[49] See, MDPP Billing and Claims Cheat Sheet, available at https://innovation.cms.gov/innovation-models/medicare-diabetes-prevention-program. As of 2021, "ongoing maintenance" – or the delivery of a second 12-month period of MDPP – is no longer a covered benefit.

[50] 42 CFR §§ 410.130, 410.134.

[51] Medicare National Coverage Determinations Manual, Ch. 1, Part 3, § 180.1.

[52] 42 CFR § 410.132(b)(2).

[53] 42 CFR § 410.132(b)(3).

[54] Medicare National Coverage Determinations Manual, Ch. 1, Part 1 § 40.1.

[55] 42 CFR § 410.141(b)(2).

to assess the beneficiary's training needs. When no group session is available within two months of the date on which DSMT is ordered, individual training may be used when the beneficiary's condition requires it.[56] Follow-up DSMT training, by contrast, is limited to two hours total of either individual or group training per year.[57]

The training itself may be provided by a physician, but may also be provided by an individual or entity that provides other services paid for directly by Medicare. To be approved as a diabetic trainer, the trainer must submit necessary documentation, meet certain quality standards, be accredited by an approved accreditation organization, and provide documentation including outcome measurements as required by the applicable regulations.[58]

As noted above, the types of services that are covered under Medicare Part B are controlled by statute and regulation, granting CMS relatively little flexibility to deviate from those requirements. As a result, the possible range of services that can address SDOH and which are also covered under Part B are limited. It would take an act of Congress to alter the scope of covered services. Although CMS has some ability to adjust its regulations, such changes may be subject to court scrutiny and possible reversal if they are determined to fall outside the scope of the authority granted to the agency by Congress.

C. Medicare Advantage.

In contrast to Medicare Part B, the Medicare Advantage program is a more flexible program administered by private insurance companies who are themselves required to meet regulatory requirements. The program operates as a hybrid of public insurance paid for by CMS, and private insurance paid for by the individual beneficiary. Medicare Advantage program insurers are required to offer plans for purchase which cover Medicare Part B services, but also are permitted to offer a range of additional services. Many insurers have begun to offer plan benefits designed to address SDOH, especially with respect to food, nutrition, and diet. This is done through several different mechanisms, including Supplemental Benefits, and Special Needs Plans (SNPs). The increased attention to SDOH is helpful for physician practices that treat a Medicare Advantage population, especially when they take full or partial risk for their patients. Even if the practice itself is not reimbursed directly for helping the patient take advantage of these programs, improving the patient's overall health can help reduce patient expenses and thereby increase the amounts retained by the practice.

[56] 42 CFR § 410.141(c)(1).

[57] 42 CFR § 410.141(c)(2).

[58] 42 CFR § 140.141(e). Quality standards can be found at 42 CFR § 410.144. Approved entities must meet the requirements found at 42 CFR § 410.145. Outcomes measurements can be found at 42 CFR § 410.146.

Supplemental Benefits are additional benefits that may be offered to a Medicare Advantage enrollee by the Medicare Advantage plan itself, rather than by CMS.[59] These Supplemental Benefits are paid for entirely by the enrollee of the plan, and may not include either Medicare Part A or Part B benefits.[60]

Prior to 2018, CMS required Medicare Advantage plans to offer every enrollee access to the same benefits at the same level of cost sharing (i.e., the same copays or deductibles). The range of Supplemental Benefits that plans can offer was expanded with the passage of the Bipartisan Budget Act of 2018 (BBA).[61] The new provisions of the 2018 BBA permitted Medicare Advantage plans to cover as Supplemental Benefits more services for those enrollees who are chronically ill, including potential benefits that could be designed to address SDOH. The expanded range of benefits may be designed by the plans to be more customized to their beneficiaries, and were offered beginning in 2020.

Plans can now offer Supplemental Benefits tailored to meet specific medical criteria, as long as they are offered to similarly situated enrollees who are treated the same, and there is a "nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state."[62] In practical terms, as the regulators describe, the changes mean that a Medicare Advantage plan may, for example, offer reduced copays and deductibles for endocrinologist visits or more frequent foot exams for diabetic enrollees.[63] Prior to 2018, the plan would either have to offer these same benefits to <u>all</u> enrollees, or not offer such benefits to <u>any</u> enrollees.

The 2018 BBA changes allow Medicare Advantage plans to offer chronically ill supplemental benefits, made available to enrollees with one or more co-morbid and medically complex chronic conditions. The regulations require that the condition be (1) life-threatening or significantly limiting of overall health or function; (2) pose a high risk of hospitalization or other adverse health outcome; and (3) require intensive care coordination.[64] The regulations explicitly recognize that a plan "may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall functions could be improved or maintained" by receiving access to the chronically ill supplemental benefits.[65] The benefits themselves must have "a reasonable expectation

[59] 42 CFR 422.102.

[60] Medicare Managed Care Manual, Ch. 4 § 30.1.

[61] P.L. 115-123.

[62] 42 CFR § 422.100(d)(2)(ii).

[63] 83 Fed. Reg. 16480 (April 16, 2018).

[64] 42 CFR § 422.102(f).

[65] 42 CFR § 422.102(f)(2)(iii).

of improving or maintaining the health or overall function of the enrollee," and "may also include a benefit that is not primarily health related."[66]

The revisions appear to be quite popular with Medicare Advantage plans. In response to the 2018 rule change, 245 plans offered a special Supplemental Benefit for the chronically ill in 2020, with the number of plans increasing more than three times over to 845 separate plans by 2021.[67] The types of Supplemental Benefits offered by Medicare Advantage plans in the wake of the 2018 BBA changes include pest control, food and produce, meals, non-medical transportation, and service dog support.[68] Payors such as Humana and UnitedHealthcare have also worked with programs like Meals on Wheels, or provided food cards to plan enrollees.[69]

In addition to Supplemental Benefits, Medicare Advantage payors have further flexibility in addressing SDOH by offering Special Needs Plans (SNPs) to enrollees. Unlike Supplemental Benefits, however, SNPs are more restricted with respect to program eligibility. They are only made available to individuals who qualify as special needs patients, specifically those who are institutionalized or institutionalized-equivalent, are entitled to Medicaid, or have a severe or disabling chronic condition and would otherwise benefit from enrollment in an SNP.[70] An SNP may include any type of coordinated care plan that exclusively enrolls eligible individuals (as described herein), and which is also approved by the National Commission on Quality Assurance.[71]

Although there are multiple types of SNPs, including those for dual-eligible beneficiaries (D-SNPs) and beneficiaries with chronic conditions (C-SNPs), this article is focused on C-SNPs given the nexus between chronic health conditions and SDOH. C-SNPs are available only for certain conditions, including: chronic alcohol and other drug dependence; certain autoimmune disorders (e.g., rheumatoid arthritis, systemic lupus erythematosus, etc.); cancer; dementia; chronic heart failure; end-stage renal disease requiring dialysis; HIV/AIDS; neurologic disorders (e.g., ALS, epilepsy, etc.); stroke; and

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[66] 42 CFR § 422.102(f)(1)(ii).

[67] "Innovative Approaches to Addressing Social Determinants of Health for Medicare Advantage Beneficiaries," Better Medicare Alliance, August, 2021, p. 13.

[68] Kornfield, Thomas, Matt Kazan, et al., "Medicare Advantage Plans Offering Expanded Supplemental Benefits: A Look at Availability and Enrollment," Commonwealth Fund, February, 10, 2021, available at, https://www.commonwealthfund.org/publications/issue-briefs/2021/feb/medicare-advantage-plans-supplemental-benefits.

[69] "Innovative Approaches to Addressing Social Determinants of Health for Medicare Advantage Beneficiaries," Better Medicare Alliance, August, 2021, pp. 9, 15.

[70] 42 CFR § 422.2.

[71] 42 CFR § 422.4(a)(iv).

diabetes mellitus.[72] A C-SNP may target any one such condition, or may group conditions together when the conditions themselves are co-morbid and clinically linked in one of the following five multi-condition groups: (1) diabetes mellitus and chronic heart failure; (2) chronic heart failure and cardiovascular disorders; (3) diabetes mellitus and cardiovascular disorders; (4) diabetes mellitus, chronic heart failure, and cardiovascular disorders; and (5) stroke and cardiovascular disorders.[73] Medicare Advantage plans are also permitted to create their own multi-condition chronic SNPs for enrollees who have all of the qualifying commonly co-morbid and clinically linked chronic conditions in the customized chronic SNP, although the groupings are limited to the list of chronic conditions.[74]

With respect to SDOH, C-SNPs may offer meal services as well as nonmedical transportation, although these services are usually intended for post-hospitalization care or to assist the patient in connection with a specific health event, rather than providing an ongoing benefit to the patient. As a result, most meal service benefits are limited to 30 or fewer days. Nevertheless, meal plans are becoming more common within SNPs, and may also include fresh food and produce, as well as trips to the grocery store as part of the nonmedical transportation benefit. In 2020, Medicare Advantage organizations providing SNPs included meal services more frequently than non-SNP plans, and usually offered more generous meal benefits in terms of duration and number of meals provided.[75]

D. Medicaid Efforts Through Waivers.

Medicare is not the only federal health care program beginning to address SDOH. State Medicaid plans have begun to tackle the impact of SDOH in their patient populations by taking advantage of several types of waivers including Section 1915(b), 1915(c), and 1115 waivers. These waiver programs can be relevant to physician practices that treat a Medicaid population, including dual-eligible beneficiaries who access both Medicare Part B or Medicare Advantage, and Medicaid. As with Medicare Advantage, while many benefits available to patients through waiver programs do not reimburse physicians directly, physicians concerned with the overall management of their patients' health – especially physicians who take risk when treating Medicare Advantage dual eligible or Medicaid managed care patients – may want to help patients take advantage of these waivers both to improve the patient's health and to help reduce their associated expenses.

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[72] For the full list of covered chronic conditions, see Medicare Managed Care Manual, Ch. 16-B § 20.1.2.

[73] See, Medicare Managed Care Manual, Ch. 16-B §§ 20.1.3, 20.1.3.1.

[74] Medicare Managed Care Manual, Ch. 16-B § 20.1.3.2.

[75] Kornfield, Thomas, Matt Kazan, et al., "Medicare Advantage Plans Offering Expanded Supplemental Benefits: A Look at Availability and Enrollment," Commonwealth Fund, February, 10, 2021, available at, https://www.commonwealthfund.org/publications/issue-briefs/2021/feb/medicare-advantage-plans-supplemental-benefits.

Unlike Medicare Part A and Part B, the Medicaid program is not directly controlled by the Federal government. Rather, the government provides block grants of money to the states, and the states may then design their own Medicaid programs, provided that such designs meet federal requirements and guidelines. Medicaid waivers are permissible deviations from these requirements. For example, state Medicaid programs must meet a "statewideness" requirement, in that the program must be available to all recipients in the state, and in all political subdivisions.[76] Another requirement is comparability of services, meaning that the services must be available in equal amounts, duration, or scope as those provided to other individuals under the plan.[77] Yet another requirement is that of choice of provider, meaning that any individual eligible for the state Medicaid program must be able to obtain services under the program from any provider who is qualified to perform the services and participates.[78]

It is not difficult to see how such requirements might limit states in designing programs that would address SDOH. The statewideness requirement, for example, would mean that a state could not, for example, design a program targeted at improving rural health. The comparability of services requirement would mean that a state could not offer to cover different services for patients with a specific health condition, such as offering meal plans akin to Medicare Advantage SNPs meant to help patients obtain food following a hospitalization. Waivers under Sections 1915(b), 1915(c), and 1115 of the Social Security Act offer greater flexibility to states in the designing of their Medicaid programs, including the ability to address SDOH more directly.

Section 1915(b)[79]waivers are designed to allow the state flexibility in creating certain provider networks and requiring patients to use those networks. Specifically, they allow the state to create a primary care case-management system, or a specialty physician services arrangement. This lets the state waive the freedom of choice requirement, and require beneficiaries to enroll in a Medicaid managed care plan or a primary care case management program. It also permits the state to restrict beneficiary choice to specific providers, such as by limiting the number or type of providers that may provide specific Medicaid services; this is done by selectively contracting with providers.

Section 1915(c)[80] waivers are sometimes referred to as "home and community-based services" (HCBS) waivers. These waivers are designed to assist Medicaid recipients who receive long-term care services and provide them with support in their home or

[76] 42 USCA § 1396a(a)(1).

[77] 42 USCA § 1396a(a)(10)(B).

[78] 42 USCA § 1396a(a)(23).

[79] 42 USCA § 1396n(b). For more on 1915(b) waivers, see, https://www.macpac.gov/subtopic/1915b-waivers/.

[80] 42 USCA § 1396n(c). For more on 1915(c) waivers, see, https://www.macpac.gov/subtopic/1915-c-waivers/.

community rather than living in an institution. Section 1915(c) waivers waive several requirements, including statewideness, comparability of services, and income and resource rules applicable in the community.

In terms of statewideness, Section 1915(c) waivers allow states to focus their waivers in geographic areas of the state where need differs or where the availability of providers differ, as opposed to offering uniform services throughout the state. With respect to comparability of services, states are permitted to structure availability of certain programs only to specific populations at risk of institutionalization or with specific diseases or conditions. Thus, a state could design a program that only focuses on the elderly, or on people with certain behavioral conditions, or on individuals with diabetes or other chronic conditions. The income and resource rules waiver allows states to offer Medicaid services to individuals who would only be eligible for Medicaid if they were in an institutional setting.[81] So, if an individual who would otherwise be institutionalized cannot qualify for Medicaid due to the financial resources of a spouse or parent, this waiver allows a state to expand Medicaid eligibility to include them in the program.

By contrast, Section 1115[82] waivers, known as "research and demonstration" waivers, are much broader. These waivers allow states to test experimental, pilot or demonstration projects that will promote the objectives of the Medicaid program. Under a Section 1115 waiver, the Secretary of Health and Human Services may waive most requirements for state plans imposed under Section 1902 of the Social Security Act[83] and federal funding may be provided for the pilot programs in cases where costs might not otherwise be matchable. Section 1115 waivers may be constructed broadly (although they do not need to be), and as a result are more commonly used to implement programs that address the impact of SDOH. The one caveat for programs established under Section 1115, however, is that the waiver is temporary and eventually expire.

Several states have created Medicaid programs under the different waivers to address SDOH, including those that touch on food and nutrition. For example, California has an HIV/AIDS waiver program, authorized under Section 1915(c), that provides several services meant to address SDOH. These include home-delivered meals, nutritional supplements, nutritional counseling, non-emergency medical transportation, and enhanced case management services.[84] California previously had a waiver in place for the San Francisco Community Living Support Benefit Waiver, which provided enhanced care

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[81] This requirement may be found at 42 USCA § 1396a(a)(10)(C)(i)(III).

[82] See 42 USCA § 1315.

[83] However, the Secretary may not waive either citizenship requirements, or the requirements of other agencies.

[84] California Waiver Factsheet, CA HIV/AIDS Waiver (0183.R05.00), available at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/CA#0431. See also, https://www.dhcs.ca.gov/services/ltc/Pages/AIDS.aspx.

coordination, home delivered meals for individuals age 65 and older and for individuals with physical or other disabilities age 21-64**,** which was also authorized under a Section 1915(c) waiver, although this program was terminated on June 30, 2017.[85]

California also has pilot programs as part of the Cal AIM 1115 Demonstration & 1915(b) waiver, which was approved as of December 29, 2021. The Section 1115 waiver demonstration alters Medi-Cal[86] "to a population health approach that prioritizes prevention and addresses social drivers of health."[87] The program includes assistance with medically tailored meals, registered dietician services to offer assistance with good nutrition and nutrition habits, nutritional assessments, and dietary counseling and education when needed. In addition, the program will provide special meals when such meals have been prescribed by a beneficiary's health care provider.[88] The goal is to transition from a Section 1115 waiver program, to a longer-term Section 1915(b) waiver program.

North Carolina's Section 1115 waiver demonstrations are the Healthy Opportunities Pilots, which are expected to begin in 2022 ***[may need to revise this if it gets off the ground by publishing time]***. The services include food and nutrition counseling consisting of helping enrollees to find food and nutrition resources (such as food pantries, farmers market voucher programs, etc.), nutrition classes, diabetes prevention programs, and fruit and vegetable prescriptions (including vouchers to be used to purchase fruits and vegetables).[89] North Carolina also has its Community Alternatives Program for Disabled Adults (CAP/DA) Waiver, which is authorized under Section 1915(c). The program provides services such as meal preparation and delivery, nutritional services, non-medical transportation services, as well as pest control, and additional services. The CAP/DA Waiver program is available to disabled adults only, age 18 and older.[90]

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[85] California Waiver Factsheet, CA San Francisco Community Living Support Benefit Waiver (0855.R00.00), available at, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/CA#0855.

[86] California's Medicaid program. See, https://www.medi-cal.ca.gov/.

[87] CMS approval letter to Jacey Cooper, December 29, 2021, p.1, available at, https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf.

[88] See, CMS approval letter to Jacey Cooper, December 29, 2021, available at, https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf.

[89] See, First Revised and Restated Attachment M: Healthy Opportunities Pilot Service Fee Schedule, available at, https://www.manatt.com/Manatt/media/Documents/Articles/NC-Pilot-Service-Fee-Schedule_Final-for-Webpage.pdf.

[90] See, Community Alternatives Program for Disabled Adults (CAP/DA), available at, https://medicaid.ncdhhs.gov/providers/programs-and-services/long-term-care/community-alternatives-program-disabled-adults-capda. See also, North Carolina Waiver Factsheet, NC CAP/DA Waiver

Washington state's waiver programs include the Medicaid Transformation Project, a Section 1115 demonstration waiver. The program was initially approved in 2017 and scheduled to end in 2021, but was recently extended for an additional year until December 31, 2022.[91] The program provides community-based care coordination services that target Medicaid beneficiaries with one or more chronic diseases or conditions, such as diabetes, heart disease, or obesity, when that condition is also associated with at least one risk factor (such as unstable housing or food insecurity).[92] The program's benefits include home delivered meals for beneficiaries and caregivers alike, through some of the programs included as part of the overall Medicaid Transformation Project (e.g., the Medicaid Alternative Care Benefits Package, or the Tailored Supports for Older Adults Benefits Package). Other benefits offered include home safety evaluations, housework, yard work, errands, and transportation in connection with the delivery of a service.[93]

IV. Legal Hurdles and Practical Challenges

Social determinants of health are likely to remain a focus for health care payors, including the federal government and state governments. As new programs are put in place, including those that address food and nutrition, current health care providers may have patients in need of support to address their own struggles with SDOH. Other providers – not merely of health care services, but of the additional services counted as addressing SDOH – may want to avail themselves of these new expansions of coverage within Medicare and Medicaid. Meal delivery services, medically tailored meal plans, non-medical transportation services, and other services designed around patients' SDOH are likely to become more prominent. Physician practices and newer providers alike will need to navigate the mire of legal issues peculiar to health care law.

For both Medicare and Medicaid services – including Medicare Advantage and Medicaid managed care plans – physician practices remain limited in the specific type of services that they can make available to patients, especially without cost or at discounted rates. This can be especially vexing if the type of service the physician wishes to offer is not itself covered by the specific plan. For example, what are the options available to a primary care physician to help a patient with type-2 diabetes, hypertension, and high cholesterol when the patient lives in a food desert or food swamp, and does not have access to transportation to take them to a supermarket? Under Medicare Part B, there is likely very little the health care provider can offer which will be covered as a Part B benefit. If the

(0132.407.00), available at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/NC#0132.

[91] See, Washington State Health Care Authority, Medicaid Transformation Project (MTP), available at, https://www.hca.wa.gov/about-hca/medicaid-transformation-project-mtp.

[92] MTP Toolkit, p.23, available at, https://www.hca.wa.gov/assets/program/wa-mtp-one-year-extension-approval.pdf.

[93] Centers for Medicare & Medicaid Services Waiver List, pp.32 and 34 of 75, available at, https://www.hca.wa.gov/assets/program/wa-mtp-one-year-extension-approval.pdf.

patient has Medicare Advantage, they may have certain Supplemental Benefits, but that will depend heavily on their particular Medicare Advantage plan. For Medicaid patients, much will depend on the state Medicaid plan and on any waiver programs that are in place. But for the primary care provider themselves, what can they do for the patient directly?

A. Beneficiary Inducements

Federal law traditionally has prohibited providers from offering direct assistance to the patient, concerned this would induce the patient to select more services from the provider than are medically necessary and thereby increase expenses to the programs in question. The primary impediment to the provider's own direct intervention in most cases remains the prohibition in the Social Security Act on beneficiary inducements. Specifically, the Act prohibits anyone from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that person knows or should know is likely to influence the beneficiary's choice of a particular provider, practitioner, or supplier of Medicare or Medicaid items or services. Violation of this prohibition can result in the imposition of civil money penalties.[94]

In 2014, following the passage of the Patient Protection and Affordable Care Act of 2010[95], the regulations governing civil money penalties were revised. The regulations changed the definition of "remuneration" to permit the delivery of certain preventive care services when such services are not connected to the provision of other services reimbursable in whole or in part by Medicare or Medicaid. The preventive services cannot include cash or cash equivalents, nor incentives that are disproportionately large as compared to the value of the preventive care services.[96] The definition of "preventive services" is the list of the United States Preventive Services Task Force.[97]

The definition of remuneration also includes a carve-out for arrangements which are permissible under "Section 1128B and its regulations," meaning that any safe harbor under the anti-kickback statute can also be used to avoid civil money penalties for possible beneficiary inducements. This is significant because there have been several safe harbors introduced over the years which can be applied to the provision of items and services that may affect SDOH for beneficiaries.

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[94] 42 USCA § 1320a-7a(a)(5).

[95] P.L. 111-148, 2010.

[96] 42 USCA § 1320a-7a(i)(6)(D); 42 CFR § 1003.110.

[97] 42 CFR § 1003.110. The full list of preventive services may be found at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations.

In 2016, after having flirted with the idea for years, the regulators added local transportation as an available safe harbor to the antikickback statute.[98] The safe harbor requires that the transportation provided not be air, luxury, or ambulance-level transportation. It must be offered based on a uniformly-applied, consistent policy that does not relate to past or possible future volume or value of federal health care program business. The transportation cannot be publicly marketed or advertised, and may only be provided to individuals who are established patients of either the provider offering the transportation, or the provider to or from which the patient is transported, or for patients who reside within 75 miles in rural areas.[99] In the preface to the regulations, the regulators explicitly allowed for the use of ride-share services.[100] Typically, such transportation is offered in relation to a medical service, and usually between the patient's residence and a health provider's office or facility. At present, the regulators have not applied the safe harbor to transportation to other places, like a food bank, a grocery store, or to allow the patient to run other errands.

In 2020, the federal antikickback regulations were revised again to add a safe harbor for providers participating in "value-based enterprises" (VBEs) to allow for "arrangements for patient engagement and support to improve quality, health outcomes, and efficiency." This safe harbor further redefines "remuneration" to not apply to patient engagement tools or supports offered by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party.[101] The regulators described examples of what might fit into the safe harbor as including the provision of in-kind transportation (such as rideshares or travel vouchers) organized by the VBE participant, grocery or meal delivery services, nutrition supplements, nutrition education, or exercise or fitness programs or equipment.[102]

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[98] For a more in-depth analysis of the local transportation safe harbor, see Gosfield, Alice G. and Daniel F. Shay, Medicare and Medicaid Fraud and Abuse, 2021 ed., Section 2:58, pp. 201-203.

[99] 42 CFR § 1001.952(bb).

[100] 85 Fed. Reg. 77863 (December 2, 2020).

[101] 42 CFR § 1001.952(hh). For a more in-depth examination of this safe harbor, see Blanchard, Timothy, and Manning, "New Opportunities for Providers Addressing Social Determinants of Health: the Patient Engagement and Support Arrangements Safe Harbor," Health Law Handbook, 2021 ed., pp. 116-179. See also, Gosfield, Alice G. and Daniel F. Shay, Medicare and Medicaid Fraud and Abuse, 2021 ed., Section 2:71, pp. 233-237.

[102] 85 Fed. Reg. 77795 (December 2, 2020).

B. Medicare Enrollment

Practices that wish to provide reimbursed diabetic services such as MNT, DSMT, and MDPP will need to navigate Medicare's enrollment process for diabetic counselors.[103] Enrollment in these programs requires a separate enrollment, which is different from the standard enrollment process that uses Medicare's series of CMS-855 paper forms or their equivalent within the Provider Enrollment, Chain, and Ownership System (PECOS). Instead, a different paper form – the CMS-20134 – is used, the separate enrollment is processed through PECOS, and different regulations apply.[104] Although a different form is used, many of the same types of issues that arise in other Medicare enrollment will apply here. Applicants will still need to ensure that the application itself is in the best shape possible when submitted, or risk delays in their effective date of billing privileges due to development requests. The best method for submission will still be the PECOS website, since submission using that site will result in faster processing times (which are the same as those for regular Medicare enrollments, and which are generally faster than paper application processing). The use of PECOS can also avoid disputes about whether and when the application was received by the Medicare Administrative Contractor (MAC); the same cannot be said when submitting paper applications. Changes to records must be reported timely, within 90 days of their occurrence, except for changes in ownership, diabetic coach rosters, and final adverse actions, all of which must be reported within 30 days.[105] Revalidation requests must also be responded to timely, which means that providers will still need to ensure that their PECOS account information is kept up to date, and that only current mailing addresses are used. This will avoid the scenario of a revalidation request being sent to an outdated address, resulting in the provider failing to respond and deactivation of the provider's billing privileges when no response is received by the MAC.[106]

C. HIPAA

Physician practices will, of course, have to navigate the requirements of HIPAA when providing SDOH-related services. For purposes of managing internal compliance efforts with respect to HIPAA and protected health information (PHI), most physician practices should face relatively few adjustments. Where matters will become more

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[103] For more discussions of Medicare's enrollment process overall, see Shay, Daniel, "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" Health Law Handbook, 2009 ed., pp. 1-34; Shay, Daniel, "'Halt! Who Goes There?': Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, 2011 ed., pp. 71-102.

[104] 42 CFR § 424.205. The enrollment application may be found at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS20134, and was last updated 1/18.

[105] 42 CFR § 424.205(d)(5). For more information on the enrollment process for Diabetes Prevention Program suppliers, see Medicare Program Integrity Manual, Ch. 10 §§ 10.2.6, 10.3.2.

[106] This scenario is discussed in greater detail in Shay, Daniel, "'Halt! Who Goes There?': Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, 2011 ed., pp. 97-98.

complicated is with respect to interactions with community-based organizations (CBOs) that often must coordinate with the physician practice to deliver the actual SDOH-related service itself. The central question to be determined will be whether the CBO is a covered entity or a business associate. This question is relevant to the physician practice as well, since it necessarily informs the practice's own compliance duties under HIPAA. The definition of a covered entity includes a "health care provider" who transmits health information in electronic form in a covered transaction.[107] A "business associate" generally means a person or entity that performs a function or activity involving the use of PHI on behalf of a covered entity.[108] Determining whether an entity is a "business associate" or a "covered entity" is a fact-dependent inquiry, which can vary from one scenario to another.

For example, consider a scenario in which a state Medicaid agency develops a Section 1115 waiver demonstration to offer fee schedule based payments for non-medical transportation services provided to Medicaid beneficiaries determined to live in a food swamp or food desert. The program will reimburse drivers or ride-share companies a fixed amount per trip plus additional fees (e.g., per-mile, time-based, or a combination of the two) to drive the Medicaid beneficiaries from their residence to a grocery store where the beneficiary can shop, and back again. Would the entity providing transportation be a "covered entity"? Because the definition of a "covered entity" applies to "health care providers," this necessarily raises the question of what constitutes a "health care provider." The definition is broader than might be expected. It includes providers of services as defined under the Social Security Act, providers of medical or health services, and "any other person or organization who furnishes, bills, or is paid for health care in the normal course of business."[109] "Health care" itself, under HIPAA, is likewise defined broadly to mean "care, services, or supplies related to the health of an individual."[110] Taken together, it is possible that the entity that provides transportation could be seen as a "covered entity," although there would be some question as to whether they provide health care "in the normal course of business." Regardless, the entity would at least need to undergo such analysis, which might be for naught if the state agency responsible for administering the Medicaid program and the 1115 Waiver demonstration simply required them to comply with HIPAA as a condition of participation.

It is, however, more likely that CBOs will be business associates when they work with physician practices or other health care providers, depending on how involved the CBO becomes with actual use of PHI. Consider a scenario in which a physician practice enters into a VBE that targets a patient population of obese patients. They want to offer a food and vegetable delivery service. They may partner with a delivery service to bring food from local farms to patients' homes. In such circumstances, the delivery service will likely

[107] 45 CFR § 160.103. The covered transactions can be found in the same section.

[108] For the full definition, see 45 CFR § 160.103.

[109] 45 CFR § 160.103.

[110] For the full definition, see 45 CFR § 160.103.

be a business associate, since it will necessarily need PHI (e.g., patient names and addresses) to perform its function.

The CBO's status as a business associate depends heavily upon the facts, however. Consider an example in which a physician practice partners with a local food pantry to provide healthy meals to patients. In one scenario, the physician practice could provide cards to their patients to claim meals at the pantry. When the patient presents the card, they are given the meal, with no further questions asked. In this case, the pantry would likely not be seen as a business associate. The pantry would have little access to PHI beyond the patient's visual appearance. More importantly, however, the pantry would not be performing a service *on behalf of* the covered entity physician practice; it would perform its services on behalf of itself or the patient. If, on the other hand, the practice worked with the pantry to collect data on the patient items the patient selected from the pantry, how often the patient visited, what time of day and/or what days of the week the patient visited, etc., with the pantry sending this data to the practice electronically, then the pantry would be working as a business associate on the practice's behalf.

Understanding these factors is crucial for the practice's own compliance efforts, since the practice has a duty under HIPAA to enter into business associate agreements with its business associates.[111] This necessarily means the practice must know when an entity is, in fact, a business associate. Likewise, this is important for the CBOs involved, since they may have little or no experience with HIPAA.

D. Indirect Benefits

Physician practices may also struggle with other aspects of SDOH-related services. First, many such services are not directly reimbursable to the practice itself. While it is true that certain Medicare Part B services, such as MNT, DSMT, and the MDPP are reimbursed directly to the practice, the supplemental benefits offered by a Medicare Advantage plan, or the benefits offered under a Section 1915(c) or Section 1115 waiver plan in Medicaid may not be. For example, payors may reimburse local transportation in certain circumstances, but that payment is made to the entity performing the transportation, not to a physician practice that merely arranges for such transportation for their patients. Home delivery of meals may be a plan benefit under a Medicare Advantage SNP, but payment will be made to the provider of food and/or the delivery service, rather than the health care provider that orders the service unless the ordering provider is also able to provide the food delivery service or contract to have it provided under the health care provider's aegis. This will likely raise the question of whether it makes economic sense for the practice to pursue SDOH-related services. For practices that operate primarily on a fee-for-service basis, it may not. For practices that receive risk-based payments – either full or partial in nature – it may make more sense to provide SDOH-related services as a cost-saving effort.

[111] Required under 45 CFR § 164.502(e)(2).

Even for practices where it is financially beneficial to provide or arrange for SDOH-related services, it is likely that such efforts will be time-consuming, difficult to navigate, and will impose administrative burdens on the practice. We represent a primary care group that has agreed to take full risk with certain payors, and has taken a keen interest in SDOH-related services. The client does not directly provide many of these services (although they do directly employ nutritionists and social workers), but they do arrange for the provision of things like meal plans and housing for some of their patients. As a result, the client has had to dedicate staff to these efforts. Many of their patients do not even know the benefits available under their respective plans, and many do not even have the capacity to discover this information. For example, if the plan offers SDOH-related services but puts that information on their website, it is presuming that the patients first, have access to a computer or smartphone to view the website in the first place, and second, that the patients will have the wherewithal and technological knowhow to do so, which may not be the case. As a result, determining a patient's benefits may fall to the practice.

Even assuming the patient's plan offers the relevant benefit, the practice still has to then navigate questions of eligibility for the benefit itself. Again, the patient may be in no position to determine their own eligibility. Doing so may require greater health literacy than the patient has, as well as – again – the tools necessary to access the information in the first place (e.g., a computer or smartphone). Once again, the practice must dedicate staff to determining patient eligibility. If the patient is eligible, they may not be automatically enrolled in the benefit and may need to complete documentation to that effect, necessitating further practice staff involvement to assist the patient in the application process. None of this work is compensated by the payors; the practice must take on all of these costs. For a full-risk practice, this makes sense. Maintaining the patients' health is both an ethical goal, and one that helps the practice's bottom line. But for practices that do not take full risk, or take no risk at all, such efforts may be too great an economic burden.

E. Documentation

Documentation of SDOH-related services may also create difficulties for health care providers. For example, if in the course of treating the patient, the patient states that they are food insecure, live in a food desert, are homeless, or otherwise face SDOH that could negatively impact the patient, it could create concerns surrounding documentation and providing patients the appropriate level of care. The provider will likely want to document the patient's condition to create a more complete record. But this raises the question as to what, if anything, the provider does in response, which itself raises the question of whether the response meets the standard of care for malpractice purposes. As more and more providers confront patient SDOH and attempt to develop treatment and other responses to them (e.g., referral to a food pantry, or an organization that provides affordable housing, etc.), this may shift the standard of care to where providers can no longer ignore SDOH nor leave it out of documentation entirely. In other words, while it may not be relevant for every type of provider, many providers will no longer be able to claim that such issues are outside of their bailiwick.

V. Conclusion

While the concept of social determinants of health is not, itself, new, the federal government and other payors (e.g., Medicare Advantage plans) are gradually shifting focus to address them. The federal government's own approach itself is slow-moving, and to some degree hampered by Congressional gridlock and the shifting priorities of presidential administrations. Still, addressing SDOH is likely to be seen as a kind of preventive medicine, which can help to reduce overall costs. As the American population grows older and therefore more reliant upon government-funded health care programs, it will likely lead to greater efforts to respond to SDOH. Given the economic impact of conditions such as diabetes, hypertension, and obesity, these efforts will likely seek to address diet, nutrition, and food availability. Certainly, the opportunity to make meaningful improvements in this area is there. For the time being, this necessarily will require health care providers to navigate the countervailing forces of efforts to control cost through utilization reduction that take shape in laws like prohibitions on beneficiary inducements. Given that fee-for-service as a payment scheme seems unlikely to disappear, it will naturally create tension with efforts to confront SDOH. Health care providers, and especially newer entities that may seek to provide SDOH-related services, will need careful guidance to navigate these waters.