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3 The Missing Puzzle Piece: Using Health Data to Close the Social Determinants of Health Gap

*Melissa A. Soliz, Eric Setterlund,
Annie Harrington, and Sarah Y. Raybin*

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The Missing Puzzle Piece: Using Health Data to Close the Social Determinants of Health Gap

Melissa A. Soliz, Eric Setterlund, Annie Harrington,
and Sarah Y. Raybin

ABSTRACT: Social determinants (or drivers) of health (SDOH) can create substantial barriers to an individual’s overall health and wellbeing. For example, several factors associated with economic hardship—lack of transportation, safe housing, or access to nutritious food, *etc.*—are highly correlated with poor health outcomes. Research demonstrates that properly addressing SDOH issues can be more impactful on an individual’s overall health rather than simply promoting healthy lifestyle choices or even by offering greater access to services. Various stakeholders have ramped up their focus to identify and address SDOH needs to improve patient care and achieve better patient outcomes. However, effectively addressing SDOH needs within the larger context of whole person care can be quite the jigsaw puzzle. In addition to technological challenges in collecting and sharing necessary data, many laws restrict the ability to collect and share data amongst all stakeholders. At times, the overall picture of “health” of a person has many missing data pieces. In this article, we explain SDOH and its importance, provide an overview of SDOH developments in the United States, and discuss relevant legal and technological issues that arise and offer some best practices to navigate them.

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Using Health Data to Close the Social Determinants of Health Gap

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THE SDOH PUZZLE PIECE: UNDERSTANDING HOW SDOH FITS INTO WHOLE PERSON CARE

To understand the complex legal puzzle involved with sharing health information to achieve whole person care (discussed in greater detail in *How to Solve the Puzzle: Solutions from the Legal Perspective* on page 32), it is necessary to first understand what social determinants of health (SDOH) are, why it is important to health outcomes, and the variety of stakeholders involved in implementing SDOH solutions. As illustrated in this section, whole person care requires a community-based approach with bidirectional data sharing that goes well beyond a person's health care providers and health plan.

What is SDOH and Why is it Important?

It is widely recognized that SDOH—“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”—have a significant impact on individual health, quality-of-life, outcomes and risks.¹ Healthy People 2030, the United States' 10 year plan for addressing the most critical health priorities and challenges published by the Department of Health and Human Services (HHS), groups SDOH into five domains² and offers the following examples of such conditions:

- Safe housing, transportation, and neighborhoods;
- Racism, discrimination, and violence;
- Education, job opportunities, and income;
- Access to nutritious foods and physical activity opportunities;
- Polluted air and water; and
- Language and literacy skills.³

1 *Social Determinants of Health at CDC*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/about/sdoh/index.html> (last reviewed Dec. 8, 2022); *see also* WHO COMM'N ON SOC. DETERMINANTS HEALTH, CLOSING THE GAP IN A GENERATION: HEALTH EQUITY THROUGH ACTION ON THE SOCIAL DETERMINANTS OF HEALTH. FINAL REPORT EXECUTIVE SUMMARY 1 (2008), https://iris.who.int/bitstream/handle/10665/69832/WHO_IER_CSDH_08.1_eng.pdf?sequence=1.

2 The five domains are Economic Stability; Education Access and Quality; Health Care Access and Quality; Neighborhood and Built Environment; Social and Community Context. *See* U.S. Dep't of Health & Hum. Servs., Off. Disease Prevention & Health Promotion, *Social Determinants of Health*, HEALTHY PEOPLE 2030, <https://health.gov/healthypeople/priority-areas/social-determinants-health> (last visited Dec. 5, 2023).

3 *Id.*; *see also* WHO COMM'N ON SOC. DETERMINANTS HEALTH, CLOSING THE GAP IN A GENERATION: HEALTH EQUITY THROUGH ACTION ON THE SOCIAL DETERMINANTS OF HEALTH. FINAL REPORT EXECUTIVE SUMMARY 1 (2008), https://iris.who.int/bitstream/handle/10665/69832/WHO_IER_CSDH_08.1_eng.pdf?sequence=1.

Graphic 1. Healthy People, Social Determinants of Health⁴



The World Health Organization’s (WHO) Commission on Social Determinants of Health cites a growing body of evidence that social determinants can have a greater influence on health than health care or lifestyle choices.⁵ The WHO estimates that the contribution from sectors *outside* of the health care sector exceeds the contribution from the health care sector.⁶ For example, when individuals lack access to grocery stores with healthy food, those individuals are less likely to have good nutrition, thereby raising the risk of health conditions like heart disease, diabetes and obesity. To effectively treat a diabetic individual living without stable housing or an obese child living with limited access to healthy food, clinicians must

4 U.S. Dep’t of Health & Hum. Servs., Off. Disease Prevention & Health Promotion, *Social Determinants of Health*, HEALTHY PEOPLE 2030, <https://health.gov/healthypeople/priority-areas/social-determinants-health> (last visited Dec. 5, 2023).

5 *Id.* See also Paula Braveman & Laura Gottlieb, *The Social Determinants of Health: It’s Time to Consider the Causes of the Causes*, 129 (Suppl. 2) PUB. HEALTH REPS. 19 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863696/>.

6 *Social determinants of health*, WHO, https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1 (last visited Dec. 5, 2023).

look beyond the traditional medical interventions and engage social services organizations to help address the housing needs or nutritional requirements that underlie or exacerbate a condition. And ultimately, the ability to share patient information and connect patients with service providers outside of the health care sector is critical to addressing the social factors and dynamics that impact their health.

Health Equity, Health Equality, and SDOH: What is the Difference?

SDOH is sometimes used interchangeably with the terms “health equity” or “health equality.” However, “health equality” and “health equity” are fundamentally different concepts, and SDOH is only one component or means to advance health equity.

Health equality refers to everyone getting the same thing regardless of individual health needs. Health equity refers to everyone getting what they need based on who they are and the circumstances in which they live.⁷ The Centers for Disease Control and Prevention (CDC) defines “health equity” as the “state in which everyone has a fair and just opportunity to attain their highest level of health.”⁸ If health equity is the ideal downstream state for health care outcomes, then health care services and social supports are upstream conditions that, if lacking, can serve as barriers to achieving health equity.

Who is Responsible for Addressing SDOH?

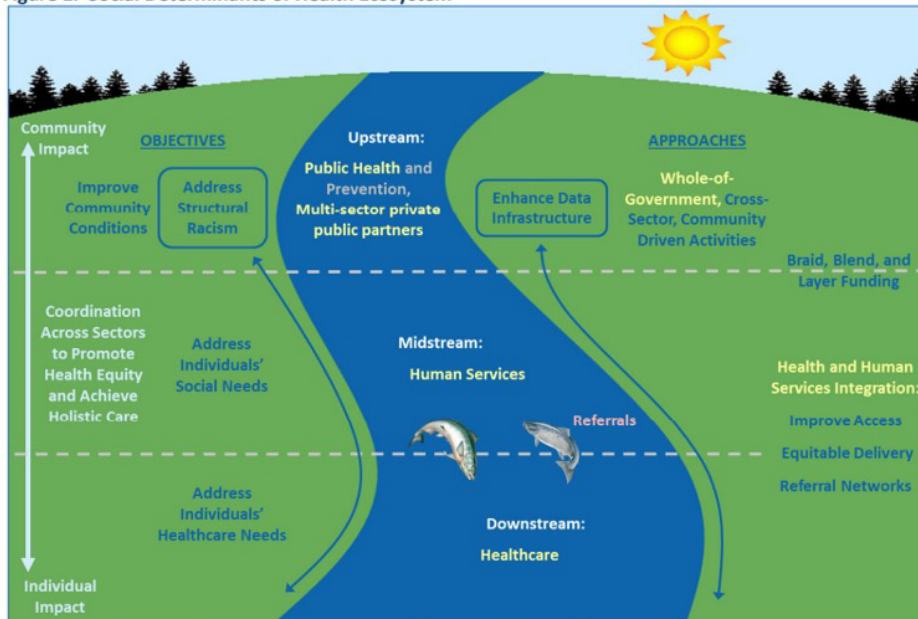
Advancing health equity through addressing SDOH requires a whole community approach. The Assistant Secretary for Planning and Evaluation (ASPE), Office of Health Policy—the Office that provides “cross-cutting policy perspective that bridges [HHS] programs, public and private sector activities, and the research community”—advocates for joint intervention by the community, human services (*e.g.*, social service providers and community-based organizations), and the health care system. Providing effective legal counsel to these entities requires an understanding of the functions, needs, and goals of SDOH as well as the ability to navigate through an array of privacy regulations.

7 See, *e.g.*, *Visualizing Health Equity: One Size Does Not Fit All Infographic*, ROBERT WOOD JOHNSON FOUND. (June 30, 2017), <https://www.rwjf.org/en/insights/our-research/infographics/visualizing-health-equity.html>.

8 *What is Health Equity?*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchstp/health-equity/index.html> (last reviewed Dec. 16, 2022).

Graphic 2. ASPE, Social Determinants of Health Ecosystem⁹

Figure 1. Social Determinants of Health Ecosystem



Note: Adapted from Castrucci B, Auerbach J. Meeting Individual Social Needs Falls Short of Addressing Social Determinants of Health. Health Affairs Blog. January 16, 2019

Indeed, given the vast array of conditions that contribute to SDOH, cross-collaboration is a necessary component of any SDOH solution, involving individuals and entities ranging from health care systems and the patients whom they serve to all levels of government, the private sector, philanthropic organizations, and community and faith-based organizations.¹⁰

9 AMELIA WHITMAN ET AL., ASPE OFF. HEALTH POL’Y, ADDRESSING SOCIAL DETERMINANTS OF HEALTH: EXAMPLES OF SUCCESSFUL EVIDENCE-BASED STRATEGIES AND CURRENT FED. EFFORTS 3 (Apr. 1, 2022), <https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf>; see also HHS’S STRATEGIC APPROACH TO ADDRESSING SOC. DETERMINANTS OF HEALTH TO ADVANCE HEALTH EQUITY – AT A GLANCE (Apr. 1, 2022), <https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf>.

10 AM. MED. ASS’N, REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE: HEALTH PLAN INITIATIVES ADDRESSING SOCIAL DETERMINANTS OF HEALTH (REFERENCE COMMITTEE A) (2020), <https://www.ama-assn.org/system/files/2020-11/nov20-cms-report-7.pdf>.

HHS’s strategic approach to SDOH, in particular, is to accomplish the following three goals:

Graphic 3. HHS SDOH Goals¹¹



Notably, each goal is grounded in bidirectional data sharing of information on individuals among a diverse set of stakeholders—each of which may be subject to different local, state, and federal laws—in order to achieve whole person care.

THE PUZZLE: STATUS OF SDOH IN THE UNITED STATES

Efforts are already well underway across the United States to address SDOH needs. In this section, we provide a survey of existing SDOH efforts, and in *Fitting the Pieces Together: Challenges to Implementing SDOH Solutions* on page 21, we discuss the challenges individuals and entities face in putting the pieces of the jigsaw puzzle together. Because the pieces often come from various different puzzle sets, they don’t always fit together and often leave stakeholders with an incomplete and frustrating picture. In *How to Solve the Puzzle: Solutions from the Legal Perspective* on page 32, we provide some best practice suggestions for how to fit the disparate pieces together and how proposed changes to these privacy laws may reshape some puzzle pieces to result in a better picture of whole person care.

¹¹ HHS’S STRATEGIC APPROACH TO ADDRESSING SOC. DETERMINANTS OF HEALTH TO ADVANCE HEALTH EQUITY – AT A GLANCE 1 (Apr. 1, 2022), <https://aspe.hhs.gov/sites/default/files/documents/aabf48cb-d391be21e5186eae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf>.

Many Pieces: Existing SDOH Solutions and Requirements

Over the last decade, stakeholders ranging from governmental actors to technology companies have devised various different solutions to completing the puzzle for whole person health, including reimbursement for SDOH activities, SDOH data collection and reporting requirements, data policies and initiatives, referral platforms and networks, and SDOH applications.

CMS SDOH Z-Codes

To facilitate the identification and tracking of SDOH issues for patients, the tenth revision of the International Classification of Diseases (ICD-10) established “Z codes.”¹² Z codes were developed to capture social, economic, or environmental risk factors that can cause patients to be at risk for poor health outcomes.¹³ These codes created a standard format to document issues such as illiteracy, unemployment, lack of housing, lack of food/water, family instability, history of abuse, and exposure to hazardous substances within the patient record.¹⁴

ICD-10 codes Z55-Z65 as shown in the Z Code Overview table on page 11 capture a variety of social and behavioral risk factors that can impact patient health outcomes.

12 See CMS MACBIS T-MSIS Reporting Reminder: Reporting ICD-10-CM Diagnosis Codes with Clarification on “Z Codes” for Social Determinants of Health (SDOH), MEDICAID.GOV, <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/105716> (last visited Dec. 5, 2023); see also CTRS. FOR MEDICARE & MEDICAID SRVS., USING Z CODES: THE SOC. DETERMINANTS OF HEALTH (SDOH) DATA JOURNEY TO BETTER OUTCOMES, <https://www.cms.gov/files/document/zcodes-infographic.pdf> (last revised June 2023).

13 CTRS. FOR MEDICARE & MEDICAID SRVS., USING Z CODES: THE SOC. DETERMINANTS OF HEALTH (SDOH) DATA JOURNEY TO BETTER OUTCOMES, <https://www.cms.gov/files/document/zcodes-infographic.pdf> (last revised June 2023).

14 *Id.*

Graphic 4. Z Code Overview

Z code Category		Description of issues covered
Z55	Problems related to education and literacy	Illiteracy or low literacy, unavailability of schooling, failure or underachievement in schools, and issues with teachers or classmates
Z56	Problems related to employment and unemployment	Unemployment, threat of job loss, changes in employment, physical and mental strain from work, conflicts with bosses and co-workers, uncongenial work environments
Z57	Occupational exposure to risk factors	Work related hazards such as exposure to noise, dust, tobacco smoke, air contaminants, toxic agents, and other risk factors
Z58	Problems related to physical environment	Inadequate drinking water supply or other environmental problems
Z59	Problems related to housing and economic circumstances	Homelessness, inadequate housing, problems associated with residential institutions, conflict with neighbors, lodgers, and landlord, extreme poverty, low income, and lack of welfare support
Z60	Problems related to social environment	Difficulties adjusting to life cycle transitions, living alone, social exclusion/rejection, adverse discrimination and persecution
Z62	Problems related to upbringing	Absence of parents, neglect, parental overprotection, children in welfare custody or institutional upbringing, history of neglect or abuse in childhood, or other conflict with parents or siblings
Z63	Other problems related to primary support group, including family circumstances	Issues with spouse/partner, absence or death of a family member, separation and divorce, dependent relative caretaking duties, addiction within family, other stressful life events affecting family
Z64	Problems related to certain psychosocial circumstances	Unwanted pregnancy, births of multiples, discord with counselors
Z65	Problems related to other psychosocial circumstances	Imprisonment, incarceration, problems related to legal circumstances, exposure to disaster, war, victims of crime and terrorism

Note: Adapted from Poland, Leigh. Leveraging RCM and Coding to Help Address the Health Equity Gap. Journal of the American Health Information Management Association Blog. September 26, 2022.

Although the Centers for Medicare and Medicaid Services (CMS) released Z codes for use during the 2016 fiscal year, utilization by providers has been slow. The National Opinion Research Center at the University of Chicago found that of 94.4 million Medicaid beneficiaries, only 1.42% had at least one Z code documented in a claim in 2018.¹⁵ CMS' Office of

15 PETRY S. UBRI ET AL., NORC AT THE UNIV. OF N. CHICAGO, THE ROLE OF STATE POLICY IN USE OF Z CODES TO DOCUMENT SOCIAL NEED IN MEDICAID DATA (Mar. 2022), https://www.norc.org/content/dam/norc-org/pdfs/The%20Role%20of%20State%20Medicaid%20Policy%20in%20Documentation%20of%20SDOH%20in%20Medicaid%20Data_032422.pdf.

Minority Health noted similar findings among Medicare recipients, with just 1.59% of 33.1 million fee-for-service beneficiaries having claims with Z codes in 2019.¹⁶ The sluggish rate of adoption for Z codes has been attributed to low provider awareness, confusion over who can document SDOH data within the patient record, lack of financial incentives, and use of screening tools which do not easily translate to Z codes.¹⁷

To address questions centered around documentation of social needs within the patient record, CMS has issued guidelines for clarification.¹⁸ The CMS guidelines state that since Z codes are intended to collect social information and not medical diagnoses, documentation from clinicians other than the patient's provider may be used to assign Z codes.¹⁹ Specifically, non-physician members of a patient's care team such as social workers, community health workers, case managers, or nurses are allowed to document social needs.²⁰ The guidance further states self-reported patient data may be used to assign Z codes if the information is incorporated into the medical record by a provider or clinician.²¹ However, Z codes themselves are not tied to direct financial reimbursement from governmental or commercial payers.

Although Z codes are not generally used for reimbursement, they can be used by payers, hospitals, and other health care delivery systems to reduce the costs of care or to receive performance-based payments through value-based care initiatives and risk adjustment models. Within the Medicaid program, several states have implemented enhanced payment methodologies and mandatory requirements to encourage collection of SDOH data to account for social and behavioral risk factors within their populations. Minnesota's Department of Human Services developed an accountable care organization (ACO) model with its Integrated Health Partnerships (IHP) program.²² Providers that participate in the IHP program can choose to receive payment adjustments based on their ability to meet health equity objectives.²³ Documentation of Z codes in this case can help obtain increased reimbursement rates for providers who handle complex patient populations such as those experiencing incarceration, behavioral health issues, or homelessness. Other states, such as

16 CTRS. FOR MEDICARE & MEDICAID SRVS., UTILIZATION OF Z CODES FOR SOCIAL DETERMINANTS OF HEALTH AMONG MEDICARE FEE-FOR-SERVICE BENEFICIARIES, 2019, 1 (Sept. 2021), <https://www.cms.gov/files/document/z-codes-data-highlight.pdf>.

17 *Resource on ICD-10-CM Coding for Social Determinants of Health*, AM. HOSP. ASS'N, <https://www.aha.org/dataset/2018-04-10-resource-icd-10-cm-coding-social-determinants-health> (last visited Dec. 5, 2023).

18 ICD-10-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING: FY 2022 – UPDATED APRIL 1, 2022 (OCTOBER 1, 2021 – SEPTEMBER 30, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

19 *Id.*

20 *Id.*

21 *Id.*

22 PETRY S. UBRI ET AL., NORC AT THE UNIV. OF N. CHICAGO, THE ROLE OF STATE POLICY IN USE OF Z CODES TO DOCUMENT SOCIAL NEED IN MEDICAID DATA 12 (Mar. 2022), https://www.norc.org/content/dam/norc-org/pdfs/The%20Role%20of%20State%20Medicaid%20Policy%20in%20Documentation%20of%20SDOH%20in%20Medicaid%20Data_032422.pdf.

23 *Id.*

Arizona, have implemented billing requirements for providers in their Medicaid programs that mandate use of Z codes in applicable claims to ensure greater documentation of SDOH for their enrollees.²⁴

CMS has also recently updated its inpatient acute hospitals Medicare fee-for-service payment rates and policies to designate diagnosis codes for patients related to homelessness as high severity.²⁵ Eligible hospitals that document Z codes related to homelessness in the patient chart can be eligible for higher payments to reflect the increased use of hospital resources.²⁶ CMS has further taken action to finalize policies in the 2024 Medicare Physician Fee Schedule to have separate coding and payment for several new services to help underserved populations, including appropriate payment for practitioners that engage with caregivers as well as community integration services, navigation services, and SDOH risk assessments.²⁷

Recent action by Congress and CMS to expand the Medicare Advantage Value-Based Insurance Design Model to all 50 states is likely to increase use of Z codes as a greater number of organizations are now eligible to participate.²⁸ This demonstration program requires participating Medicare Advantage Organizations to collect data on social determinants of health for enrollees.²⁹ It also requires participating organizations to use funding to provide supplemental benefits such as meal or grocery delivery, air conditioning, and housing assistance to enrollees with complex social needs.³⁰

As states and CMS continue to offer more incentives for collecting social needs information for patients, Z code documentation in the patient chart is likely to become more frequent.

CMS SDOH Screening Quality Measures

A recent data brief published by the Office of the National Coordinator for Health Information Technology (ONC) indicated that just 54 percent of non-federal acute care hospitals routinely reported collecting data on patients' health-related social needs. To encourage increased collection of SDOH data, CMS has also recently launched new reporting programs focused on

24 ARIZ. HEALTH CARE COST CONTAINMENT SYS., *Chapter 10: Individual Practitioner Services, in FEE-FOR-SERVICE PROVIDER BILLING MANUAL*, https://www.azahcccs.gov/PlansProviders/Downloads/FFSProvider-Manual/FFS_Chap10.pdf (last revised May 31, 2023).

25 *FY 2024 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment Sys. (LTCH PPS) Final Rule — CMS-1785-F and CMS-1788-F Fact Sheet*, CMS.gov (Aug. 1, 2023), <https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective-0>.

26 *Id.*

27 *Calendar Year (CY) 2024 Medicare Physician Fee Schedule Final Rule*, CMS.gov (Nov. 2, 2023), <https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule>.

28 *Medicare Advantage Value-Based Insurance Design Model Extension Fact Sheet*, CMS.gov, <https://innovation.cms.gov/vbid-extension-fs> (last updated Oct. 17, 2023).

29 *Id.*

30 *Id.*

SDOH data quality and collection measures. For example, in the 2023 Inpatient Prospective Payment Systems (IPPS) Final Rule, CMS has included updates to the Hospital Inpatient Quality Reporting (IQR) program that require the adoption of two new SDOH screening measures: SDOH-1, Screening for Social Drivers of Health; and SDOH-2, Screen Positive Rate for Social Drivers of Health.³¹

SDOH-1 looks to the numbers of individuals screened for SDOH, while SDOH-2 looks to the number of individuals who were positive for SDOH issues in the following five domains: food insecurity; housing instability; transportation needs; utility difficulties; and interpersonal safety. In 2023, reporting on the SDOH-1 and SDOH-2 is voluntary, but such reporting will become mandatory in 2024.³² As a new requirement for 2023, CMS also requires ACOs that participate in the Realizing Equity, Access, and Community Health (ACO REACH) Model to collect and submit demographic data annually and to “implement a robust health equity plan to identify underserved communities and implement initiatives to measurably reduce health disparities within their beneficiary populations.”³³ Participants are required to continually assess the health equity plan to ensure that it “satisfactorily meets the criteria for selected goals and measurement, while continuing to protect access and availability of services for beneficiaries, use of evidence-based interventions, community involvement, and evaluation.”³⁴ CMS is also considering more robust SDOH data submission requirements for ACO participants for future model years.³⁵ Finally, Medicare Advantage Special Needs Plans (SNPs) are required to conduct an assessment of an enrollee’s physical, psychosocial, and functional needs using a comprehensive risk assessment tool at enrollment and annually.³⁶ Starting in 2024, such assessments will include at least one question on each of the categories of housing stability, food security, and access to transportation.³⁷

31 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, 87 Fed. Reg. 48,780, 49,202–20 (Aug. 10, 2022) (to be codified at 42 C.F.R. pts. 412, 413, 482, 485, & 495).

32 *Id.*

33 *Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model*, CMS.gov. (Feb. 24, 2022), <https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model>; *see also* COMPARING GPDC TO THE ACO REACH MODEL, <https://innovation.cms.gov/media/document/gpdc-aco-reach-comparison>.

34 PROGRAM INTEGRITY, ELIGIBILITY AND COMPLIANCE IN THE ACO REALIZING EQUITY, ACCESS, AND COMMUNITY HEALTH (ACO REACH) MODEL: AN OVERVIEW OF THE MODEL’S VETTING, MONITORING, AUDITING AND ANALYTIC ACTIVITIES 2, <https://innovation.cms.gov/media/document/aco-reach-mont-comp-ovw>.

35 CMS/CMMI, ACO REALIZING EQUITY, ACCESS, AND COMMUNITY HEALTH (REACH) MODEL: HEALTH EQUITY UPDATES WEBINAR (Apr. 5, 2022), <https://innovation.cms.gov/media/document/aco-reach-health-equity-slides>.

36 *CY 2023 Medicare Advantage and Part D Final Rule (CMS-4192-F)*, CMS.gov (Apr. 29, 2022), <https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-final-rule-cms-4192-f>.

37 *Id.*

Other SDOH Data Policies and Initiatives

HHS through the Office of the National Coordinator of Health Information Technology is also striving to advance health equity and SDOH solutions through its data policies and initiatives. In February of 2022, ONC announced its commitment to “health equity by design”—the concept of mobilizing health information technology (IT) to identify and mitigate health disparities.³⁸ ONC is using this concept to drive its data policies and health IT regulations, including updates to the United States Core Data for Interoperability (USCDI) and requirements for certified electronic health records (EHRs).

The USCDI is a standardized set of health data classes, data elements and vocabulary standards (aka content) to support nationwide, interoperable health information exchange.³⁹ In layperson’s terms, it is the common language that technologies can use to communicate with one another. Without this standardized content, different data systems, networks, or platforms may contain important information about an individual but be incapable of sharing that information with each other because each system, network, or platform is using its own proprietary language.

In July of 2021, ONC finalized version 2 of the USCDI, which included new data elements to capture a patient’s sexual orientation and gender identity (SOGI) and SDOH needs.⁴⁰ Specifically, ONC finalized the following SDOH and SOGI data elements in version 2:

- SDOH Assessment
- SDOH Goals
- SDOH Problems/Health Concerns
- SDOH Interventions
- Gender Identity
- Sexual Orientation⁴¹

And the USCDI continues to evolve through public/private collaborations, like the Gravity Project and Project US@. The Gravity Project is a collaboration of interested stakeholders whose mission is to develop and advance open data standards using HL7® FHIR (Fast Healthcare Interoperability Resources) to support the collection, use and exchange of

38 Ryan Argentieri et al., *Embracing Health Equity by Design*, HEALTHITBUZZ (Feb. 22, 2022), <https://www.healthit.gov/buzz-blog/health-it/embracing-health-equity-by-design>.

39 See *United States Core Data for Interoperability (USCDI)*, HEALTHIT.GOV, <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi> (last visited Dec. 5, 2023).

40 OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI) VERSION 2 (July 2021), <https://www.healthit.gov/isa/sites/isa/files/2021-07/USCDI-Version-2-July-2021-Final.pdf>.

41 OFF. OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., ONC HEALTH IT STANDARDS BULLETIN 4 (July 2021), https://www.healthit.gov/sites/default/files/page/2021-07/Standards_Bulletin_2021-3.pdf.

data to address SDOH.⁴² Project US@ is focused on improving data integrity and patient matching through the development of a unified, cross-standards specification for patient addresses—a necessary predicate to any SDOH interoperability solution that seeks to match individuals across different systems, platforms and technologies.⁴³ Indeed, versions 3 and 4 of the USCDI continue to build out the scope of data classifications, data elements and specific technical specifications and implementation guides (IGs) to better support SDOH and public health use cases based, in part, on the work produced by the Gravity Project and Project US@.⁴⁴ For example, version 3 added a data element for “reason for referral”⁴⁵ and version 4 reclassified “SDOH assessments” into the category for health status assessments.⁴⁶

ONC’s efforts at establishing data standardization is foundational to enabling the SDOH referral platforms, networks, and applications discussed below to be interoperable with existing health IT systems. Importantly, the USCDI is only a data policy. Its existence does not compel compliance. However, HHS mandates compliance with the USCDI for certain HHS-regulated programs. For example, ONC requires that health IT developers of certified health IT, including certified EHRs, support certain versions of the USCDI.⁴⁷ Likewise, CMS similarly requires USCDI version support by certain CMS-regulated payers to meet CMS interoperability mandates.⁴⁸

ONC has thus proposed in its April 18, 2023 Notice of Proposed Rule Making for Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) to require certified EHRs to support the access, exchange, and use of the full range of data elements listed in the USCDI v3, which includes the SOGI and SDOH data elements described above.⁴⁹ Additionally, ONC proposed in HTI-1 to require health IT developers that support clinical decision support (CDS) applications (aka decision support interventions or DSI) to require such applications to disclose which source attributes (*e.g.*, data elements relevant to health equity) are considered for purposes of the

42 See Carrie Lousberg, *The Gravity Project*, CONFLUENCE, <https://confluence.hl7.org/display/GRV/The+Gravity+Project> (last modified Oct. 18, 2023).

43 See Carmen Smiley, *Project US@*, ONC TECH LAB STANDARDS COORDINATION, <https://oncprojecttracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153> (last modified Jan. 19, 2023).

44 See, *e.g.*, Carmen Smiley & Julie Pursley, *Project US@ – Advancing Health Equity Requires Better Data*, HEALTHITBUZZ (Aug. 9, 2022), <https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/project-us-advancing-health-equity-requires-better-data>; Ryan Argentieri et al., *Embracing Health Equity by Design*, HEALTHITBUZZ (Feb. 22, 2022), <https://www.healthit.gov/buzz-blog/health-it/embracing-health-equity-by-design>.

45 OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., ONC HEALTH IT STANDARDS BULLETIN 4 (July 2022), https://www.healthit.gov/sites/default/files/page/2022-07/Standards_Bulletin_2022-2.pdf.

46 OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., ONC HEALTH IT STANDARDS BULLETIN 6 (Jan. 2023), https://www.healthit.gov/sites/default/files/page/2023-01/Standards_Bulletin_2023-1.pdf.

47 See, *e.g.*, 45 C.F.R. § 170.213 (2023).

48 See, *e.g.*, 42 C.F.R. § 422.119(c)(3)(i).

49 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. 23,746 (proposed Apr. 18, 2023) (to be codified at 45 C.F.R. pts. 170 & 171).

CDS solution to allow users to better understand whether the CDS solution adequately considers the individual patient's needs.⁵⁰

Other HHS-related or -mentioned working groups that are advancing SDOH (or SDOH-related) data policies and initiatives include (but may not be limited to) the following:

- The SDOH Clinical Care FHIR Implementation Guide to exchange SDOH content as defined by the Gravity Project;⁵¹ ONC's 360X Project to develop technical standards to support closed loop referrals from the EHR to social service agencies; and ONC's Leading Edge Acceleration Projects (LEAP) awards, which included awards in 2022 to Alliance Chicago and in 2021 to the University of Texas at Austin to develop integrated SDOH solutions.⁵² We discuss the development of SDOH referral platforms and networks, as well as SDOH applications, in more detail in SDOH Referral Platforms and Networks on page 18 and in Other SDOH Applications on page 20.
- The Sync for Social Needs Initiative, which is committed to developing consensus on standards and piloting real-world testing of a HL7[®] FHIR-based approach for the collection and sharing of social needs screening results to meet CMS SDOH reporting requirements.⁵³
- ONC's USCDI+, a service ONC provides to federal and industry partners to advance USCDI data elements to meet specific programmatic and use case needs. USCDI+ efforts are currently focused on advancing quality measurement and public health with HHS, CDC and Health Resources and Services Administration (HRSA).⁵⁴
- The Gender Harmony Project to accurately capture and represent sex and gender concepts, such as gender identity, sex for clinical use, recorded sex or gender, name to use, and pronouns.⁵⁵
- The Helios FHIR Accelerator for Public Health, which is a HL7, CDC, and ONC initiative to standardize the content needed to support public health use cases.⁵⁶

50 *Id.* at 23,748–49.

51 *SDOH Clinical Care 2.1.0 STU 2.1*, HL7 INT'L: GRAVITY PROJECT, <https://hl7.org/fhir/us/sdoh-clinicalcare/> (last updated July 27, 2023).

52 *Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT)*, HEALTHIT.GOV, <https://www.healthit.gov/topic/leading-edge-acceleration-projects-leap-health-information-technology-health-it> (last reviewed Sept. 26, 2023).

53 Charles Jaffe, *Sync for Social Needs*, HL7 INT'L (Sept. 28, 2022, 11:06 AM), <https://blog.hl7.org/sync-for-social-needs>.

54 *USCDI+*, HEALTHIT.GOV, <https://www.healthit.gov/topic/interoperability/uscdi-plus> (last reviewed June 28, 2023).

55 Rob McClure, *The Gender Harmony Project*, CONFLUENCE, <https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project> (last modified Oct. 3, 2023).

56 Joshua Procius, *Helios FHIR Accelerator for Public Health Home*, CONFLUENCE (May 1, 2023), <https://confluence.hl7.org/display/PH>.

- The CDC SDOH/public health use cases, which include (1) “Community Health Needs Assessment[s] . . . Leveraging Individual Level Social Care Data”; (2) “Assessment of State, Local and Territorial Health Department Diabetes Programs”; and (3) “Monitoring Federal Program Successes for Individual, Program, and Population Health Advancement.”⁵⁷
- The STAR HIE Program, which is a cooperative agreement program designed to support the ability of health information exchanges (HIEs) to support public health agencies in their response to public health emergencies and pandemics.⁵⁸
- The Public Health Informatics & Technology (PHIT) workforce development program to “increase representation of underrepresented communities within the public health IT workforce.”⁵⁹

SDOH Referral Platforms and Networks

While SDOH data policies and initiative are critical to establishing a common language for the access, exchange and use of the SDOH data, they are not an end unto themselves. Rather, they are a means to an end. Over the last decade, multi-stakeholder approaches to addressing SDOH have facilitated the creation of web-based, closed loop referral systems and SDOH data sharing networks (aka community health exchanges or social health information exchanges). These systems and networks are designed to enable health care providers—who screen patients for social needs—to use a web-based, electronic platform to refer these patients to community or faith-based organizations (collectively, CBOs) that provide assistance with food, housing, transportation, employment and other opportunities. These CBOs then close the loop by conveying the outcome of the referral and the services provided to ensure the patient receives necessary assistance. These services may also enable CBOs and the patient’s health care providers to share important information about the individual patient. For example, these platforms may make SDOH screenings and other documents accessible to all members of the individual’s care team, including CBOs, in a networked environment that effectively creates a longitudinal SDOH record for individuals.

Some state Medicaid agencies—such as the Arizona Health Care Cost Containment System (AHCCCS)—have either procured or funded closed loop referral systems to create a consolidated method for referrals from their managed care organizations and providers, as

57 Laura Beerman, *The 3 CDC SDOH Workgroup Use Cases and Why They Matter*, HEALTHLEADERS (Aug. 17, 2022), <https://www.healthleadersmedia.com/payer/3-cdc-sdoh-workgroup-use-cases-and-why-they-matter#:~:text=The%20uses%20cases%20include%20hospital,severely%20and%20disproportionately%20than%20others; see also Social Determinants of Health at CDC, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/sdoh/index.html> (last reviewed Dec. 8, 2022).

58 *STAR HIE Program*, HEALTHIT.GOV, <https://www.healthit.gov/topic/star-hie-program> (last reviewed Jan. 19, 2023).

59 *Public Health Informatics & Technology (PHIT) Workforce Development Program*, HEALTHIT.GOV, <https://www.healthit.gov/topic/interoperability/investments/public-health-informatics-technology-phit-workforce-development> (last reviewed Feb. 2, 2023).

well as to lessen the burden on CBOs, which have limited bandwidth to work with different referral systems. In Arizona, as a component of the AHCCCS Whole Person Care Initiative (WPCI),⁶⁰ AHCCCS has partnered with the statewide HIE in Arizona to implement a statewide closed loop referral system.⁶¹ The CommunityCares system is designed to allow health care and community service providers to connect on a single statewide technology platform to improve and track the referral process between health care providers and social services, and to facilitate screening for social risk factors.⁶²

Building on these state, local, and private efforts to address SDOH through community health information exchanges and referral platforms, in February of 2023, ONC released its SDOH Exchange Toolkit—a practical guide to aid communities in launching their own SDOH platforms and networks.⁶³ It outlines the foundational considerations and best practices for implementing a SDOH exchange solution, as well as illustrative case studies. Specifically, the SDOH Exchange Toolkit outlines the following foundational elements:

- Community Readiness and Stewardship
- Mission and Purpose
- Values and Principles
- Policy
- Legal
- Measurement and Evaluation
- Financing
- Implementation Services
- Technical Infrastructure and Data Standards⁶⁴
- User Support and Learning Network
- Governance⁶⁵

60 Arizona Health Care Cost Containment System, <https://www.azahcccs.gov/AHCCCS/Initiatives/AHCCCSWPCI/> (last visited Nov. 30, 2023).

61 *CommunityCares: Arizona's Statewide Closed-Loop Referral System*, AHCCCS, <https://www.azahcccs.gov/AHCCCS/Initiatives/AHCCCSWPCI/closedloopreferralsystem.html> (last visited Dec. 5, 2023).

62 *Id.*

63 Mark Knee & Meley Gebreselassie, *New Releases: SDOH Toolkit and Learning Forum Sessions for the Health IT Community*, HEALTHITBUZZ (Feb. 22, 2023), <https://www.healthit.gov/buzz-blog/public-health/new-releases-sdoh-toolkit-and-learning-forum-sessions-for-the-health-it-community>.

64 This Section of the SDOH Exchange Toolkit draws from the content standards developed by the Gravity Project, as well as ONC's 360X project. The 360X project was specifically formed in July of 2012 to facilitate closed-loop information exchange and support patient care transitions. See *360X Home*, HEALTHIT.GOV, <https://oncproject-tracking.healthit.gov/wiki/display/TechLab360X/360X+Home> (last modified Jan. 21, 2022).

65 ONC, SOCIAL DETERMINANTS OF HEALTH INFORMATION EXCHANGE TOOLKIT: FOUNDATIONAL ELEMENTS FOR COMMUNITIES (Feb. 2023), https://www.healthit.gov/sites/default/files/2023-02/Social%20Determinants%20of%20Health%20Information%20Exchange%20Toolkit%202023_508.pdf.

It also showcases how such SDOH exchanges have been implemented by 211 San Diego HIE, CommonSpirit Health's Connected Community Network (CCN) and Social Needs Analytics (SoNA) Platform, the District of Columbia Community Resource Information Exchange (DC CoRIE), and HealthierHere in Washington state.⁶⁶ In addition to these, there is a myriad of private and commercial SDOH exchanges and network solutions being offered in the marketplace.

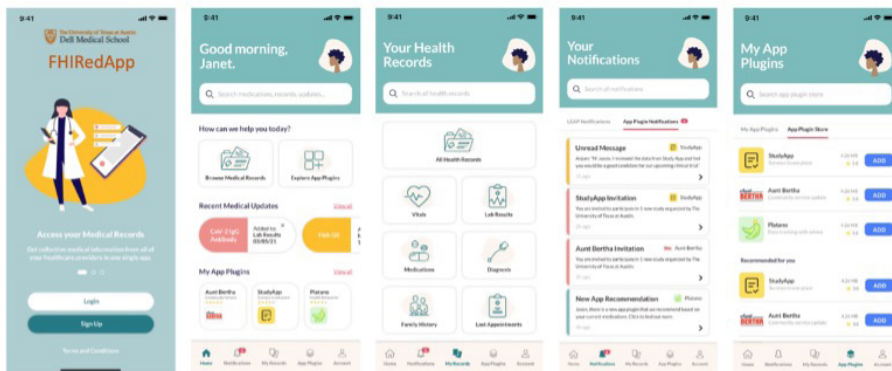
Other SDOH Applications

In addition to the SDOH referral platforms and networks, there is a wide range of SDOH consumer-facing applications available that are designed to engage patients for the purpose of collecting SDOH screenings, to connect patients directly to community or health plan/provider resources, and to provide human and non-human supports—such as chat bots or artificial intelligence—to support individual health and wellbeing. Some of these applications may be offered by technology companies on behalf of an individual's health plan or health care provider at no cost to the individual end users, while others may use a direct-to-consumer subscription model or operate as a virtual health care provider that bills for their services directly to an individual's health plan as an in-network or out-of-network provider.

For example, with its 2021 LEAP award, the University of Texas at Austin's Dell Medical School (Dell Med) developed the FHIRRedApp platform.⁶⁷ It is designed to enable patients to engage with both CBOs and health care providers using a patient-centered model that identifies the needs of a diverse range of individuals. It uses a consumer-facing model that enables the individual patient to connect to EHR endpoints to collect their medical records, receive notifications (such as lab results), and connect to other applications, such as a SDOH referral platform.

⁶⁶ *Id.* at 70–74.

⁶⁷ Ali Massihi & Wei Chang, *Where APIs meet Health Equity by Design: Introducing the FHIRRedApp Health Innovation*, HEALTHITBUZZ (Oct. 18, 2022), <https://www.healthit.gov/buzz-blog/health-innovation/where-apis-meet-health-equity-by-design-introducing-the-fhiredapp-health-innovation>.

Graphic 5. FHIRedApp High-Fidelity Prototype⁶⁸

Fitting the Pieces Together: Challenges to Implementing SDOH Solutions

Notwithstanding all of the activities and existing SDOH solutions that are currently available or under development, significant challenges exist to widespread adoption and implementation of these solutions. This section the Article will provide a high-level explanation of some of those challenges, as well as some suggestions for how these challenges may be overcome or addressed through change. Please note that is not an exhaustive or comprehensive list of issues that should be considered by individuals and entities before participating in a SDOH solution. For example, depending on the arrangement, there may be fraud and abuse or antitrust considerations that are beyond the authors' collective expertise and thus beyond the scope of this Article.

Health Data Privacy Laws

One of the most challenging aspects of implementing an SDOH solution that involves the exchange of an individual's personal information is compliance with federal and state health data privacy laws. In order to be successful, a SDOH solution requires some level of interaction and data sharing between highly-regulated health care providers and CBOs—many of which are not regulated at the federal or state level—as health care providers are—and many of which lack the resources to comply with such laws. In this section, we describe some of the challenges that exist under federal and state health data privacy laws.

⁶⁸ *Id.*

Federal health data privacy laws:

There are a number of federal health data privacy laws that apply to different types of individuals and entities that operate in the health care space:

- **The Health Insurance Portability and Accountability Act (HIPAA)** and its implementing regulations apply to health care providers that engage in HIPAA standard transactions (*e.g.*, electronically billing health plans), health plans and health care clearinghouses, and their respective business associates with respect to how they use, disclose, maintain, safeguard, and provide individual access and other rights to protected health information (PHI).⁶⁹ HIPAA is widely recognized as establishing the “floor”—that is, the minimum federal requirements—for how health information is managed in United States, including breach reporting requirements. HIPAA generally requires a patient’s written HIPAA authorization for the use and disclosure of the patient’s PHI, unless there is an exception to the authorization requirement.
- **42 U.S.C. 290dd-2 and 42 C.F.R. Part 2 (collectively, “Part 2”).** Part 2—the federal confidentiality of substance use disorder patient records—provides heightened privacy protections for patient identifying information (like PHI) that identifies a patient either directly or indirectly as having (or having had) a substance use disorder if the information originates from a Part 2 program (collectively, “Part 2 data”).⁷⁰ Part 2’s disclosure restrictions apply to Part 2 programs and other lawful holders of Part 2 data, such as third-party payers and consent-recipients of the Part 2 data who receive the legally required prohibition on redisclosure notice.⁷¹

A Part 2 program is a federally assisted substance use disorder treatment program.⁷² Examples of common Part 2 programs include medication-assisted treatment (MAT) clinics, employee substance use disorder assistance programs, chemical dependency units within a general hospital, addiction medicine specialists within a psychiatric hospital, a substance use disorder counselor at a school, or a substance use coordinator in an emergency department (ED).⁷³ Like HIPAA, Part 2 generally requires a patients’ written Part 2 consent—which is different from a HIPAA authorization—for the disclosure of a patient’s Part 2 data, unless an exception applies.⁷⁴ Unlike HIPAA, there are only a few exceptions to the Part 2 consent requirement, and there is not a general disclosure exception for non-emergency treatment, payment, or health care operations. Also, unlike HIPAA, Part 2 requires that each consent-based disclosure of Part 2 data be accompanied by a prescriptive prohibition on redisclosure notice.⁷⁵

69 45 C.F.R. § 164.104 (2023).

70 42 C.F.R. § 2.12(a).

71 *Id.* § 2.12(d)(2).

72 *Id.* § 2.11 (defining “Part 2 program”, “Program”); *see also id.* § 2.12(b) (explaining “federally assisted”).

73 *See* 42 C.F.R. § 2.12(e)(1).

74 *See id.* § 2.13(a); 42 C.F.R. pt. 2 subpts. C & D.

75 42 C.F.R. § 2.32.

- **The Federal Privacy Act.** The Federal Privacy Act and its implementing regulations apply to federal agencies, including the Veterans Administration (VA) and armed forces, and regulates how they collect, maintain, use and disclose personally identifiable information (PII) in the possession and control of these federal agencies.⁷⁶ Like HIPAA and Part 2, the Federal Privacy Act generally prohibits the disclosure of PII without an individual’s written consent, unless an exception applies.⁷⁷ And like HIPAA and Part 2, it has its own limited list of permitted exceptions for the disclosure of PII without an individual written consent, including for disclosures involving a “routine use” that is included in a published systems of records notice (SORN).⁷⁸
- **Title X Family Planning.** The embattled federal Title X family planning program makes family planning and related health services available for free or at low cost to eligible individuals, with a specific focus on addressing the reproductive health needs of adolescents.⁷⁹ The Title X regulations require Title X-funded providers⁸⁰ to keep confidential “[a]ll information as to personal facts and circumstances [about patients] obtained by the project staff”⁸¹ Like HIPAA, Part 2 and the Federal Privacy Act, the Title X regulations generally require the patient’s signed authorization to disclose health information, even if the patient is a minor, unless an exception applies.⁸² And Title X’s exceptions are limited to those disclosures that are necessary to provide services to the patient or as required by law.⁸³ Although the status of the Title X provisions regarding a minor’s right to consent to Title X family planning services without parental consent is in question after the December 2022 Texas decision in *Deanda v. Becerra*,⁸⁴ the fundamental privacy protections afforded to all Title X recipients remain.

In each instance, these federal laws impose differing requirements on when and whether health care providers and other individuals and entities subject to them may share individually identifiable health information—including patient demographics—with third parties.

For example, HIPAA permits PHI to be disclosed to third parties in certain cases without an individual’s authorization or consent. Notably, HIPAA permits covered entities to disclose PHI pursuant to the treatment and health care operations exceptions to the authorization requirement, which are viable pathways to share information with CBOs.⁸⁵ The definitions of both “treatment” and “health care operations” in HIPAA include certain case management

76 5 U.S.C. § 552a (2023); 36 C.F.R. pt. 1202.

77 See 5 U.S.C. § 552a(b).

78 See, e.g., *Protecting Veteran Privacy*, VA, https://www.oprm.va.gov/privacy/systems_of_records.aspx (last updated Oct. 25, 2023) (including a link to the current VA SORN list).

79 42 U.S.C. §§ 300–300a-8.

80 42 C.F.R. § 59.1.

81 *Id.* § 59.10(a).

82 *Id.* § 59.10.

83 *Id.* § 59.10(a).

84 *Deanda v. Becerra*, 645 F.Supp.3d 600 (N.D. Tex. Dec. 8, 2022), *judgment entered*, 2:20-CV-092-Z (N.D. Tex. Dec. 20, 2022).

85 See 45 C.F.R. § 164.506.

and care coordination activities.⁸⁶ Specifically, “treatment” is defined to include “the provision, coordination, or management of health care” while the definition of “health care operations” includes, among other things, “population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination . . . and related functions that do not include treatment.”⁸⁷ With respect to the treatment exception, HHS has provided the following guidance in response to a provider’s inquiry about sharing information with a housing provider:

A health care provider may disclose a patient’s PHI for treatment purposes without having to obtain the authorization of the individual. Treatment includes the coordination or management of health care by a health care provider with a third party. Health care means care, services, or supplies related to the health of an individual. Thus, health care providers who believe that disclosures to certain social service entities are a necessary component of, or may help further, the individual’s health or mental health care may disclose the minimum necessary PHI to such entities without the individual’s authorization. For example, a provider may disclose PHI about a patient needing mental health care supportive housing to a service agency that arranges such services for individuals.⁸⁸

It should be noted that disclosures under the health care operations exception are subject to HIPAA’s minimum necessary standard, which requires that PHI only be used or disclosed when necessary to satisfy a particular purpose or function, while treatment-based disclosures are not.⁸⁹ Additionally, while a covered entity may obtain “consent” for these treatment and health care operation activities—such “consent” is not to be confused with an “authorization;”⁹⁰ a covered entity is not legally required to obtain a patient’s HIPAA authorization for these disclosures.⁹¹ However, leveraging consent or an authorization may be appropriate depending on the circumstances or the population intended to be served. For example, several closed-loop referral systems or networks that connect HIPAA covered health care providers and health plans with CBOs and various governmental agencies have adopted an authorization-based approach to take the data sharing that occurs on these systems outside of HIPAA’s use and disclosure protections.

⁸⁶ See *id.* § 164.501 (defining “Treatment,” “Health care operations”).

⁸⁷ *Id.*

⁸⁸ Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes? For example, can a health care provider refer a homeless patient to a social services agency, such as a housing provider, when doing so may reveal that the basis for eligibility is related to mental health?, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html> (last reviewed Jan. 9, 2023).

⁸⁹ See 45 C.F.R. § 164.502(b)(2)(i).

⁹⁰ Compare *id.* § 164.506(b) with *id.* § 164.508.

⁹¹ 45 C.F.R. § 164.506(b)(1).

While the treatment and health care operations pathways appear straightforward, confusion in the health care industry led HHS, on January 21, 2021, to release a Notice of Proposed Rulemaking, in which, among other things, HHS expressly reinforced the existing treatment and health care operations pathways to use and disclose PHI to address SDOH-related issues.⁹² The proposed changes are discussed in more detail in Proposed Changes to Privacy Laws to Advance SDOH Efforts on page 35.

Another helpful HIPAA pathway for SDOH stakeholders lies in what is commonly referred to as the “Friends and Family” exception. Pursuant to this exception, a covered entity may share information to spouses, family members, friends, or other persons identified by the individual that is directly relevant to such person’s involvement with the individual’s care or payment related to the health care services.⁹³ Specifically, if the individual is present prior to a use or disclosure (and has the capacity to make health care decisions), the covered entity may use or disclose the PHI to persons involved with the individual’s care if it obtains the individual’s agreement; provides the individual an opportunity to object and the individual does not object; or reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.⁹⁴ This is very helpful in the context of a hands-on care team working with an individual to navigate SDOH-related obstacles and obtain necessary community resources.

By contrast, Part 2 does not have an exception that would allow a Part 2 program or other lawful holder to disclose Part 2 data to a CBO without a patient’s Part 2-compliant consent or the existence of a subcontractor arrangement, in which the CBO is performing services on their behalf and contractually agrees to certain Part 2 compliance requirements. The current Part 2 regulations generally require that the consent form specifically name the individual(s) or entity(ies) that will be receiving the Part 2 data.⁹⁵ Part 2 does have a consent option that would allow the sharing of Part 2 data within a networked environment (such as through a SDOH exchange) using a general designation for the class of network participants that may receive the Part 2 data (called a “general designation consent”), but the current Part 2 regulations limit that option to network participants that have a “treating provider relationship” with the patient.⁹⁶ Part 2 defines a “treating provider relationship” as:

[R]egardless of whether there has been an actual in-person encounter:

(1) A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and;

92 Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6,446 (proposed Jan. 21, 2021) (to be codified at 45 C.F.R. pts. 160 & 164).

93 45 C.F.R. § 164.510(b).

94 *Id.*

95 42 C.F.R. § 2.31(a)(4)(i).

96 *Id.* § 2.31(a)(4)(ii)(B).

(2) The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.⁹⁷

It is not clear whether all CBOs would be covered by a general designation consent given this definition of “treating provider relationship,” especially in circumstances where a Part 2 program may only be referring the patient out for CBO services and neither the patient nor the CBO has agreed to accept or provide the services. Thus, whether a CBO satisfies that definition must be determined on a case-by-case basis.

Moreover, consent-recipients of the Part 2 data must receive the legally required prohibition on redisclosure notice with each disclosure (or display) of the Part 2 data.⁹⁸ The Substance Abuse and Mental Health Services Administration (SAMHSA) explains that such notice must accompany each disclosure and cannot be satisfied through use of logon or splash page with the notice.⁹⁹

As these two examples illustrate, even at the federal level, there is not a one-size fits all solution to SDOH data exchange when the data suppliers may be subject to different federal health data laws that impose different requirements depending on who is sending the data, who is receiving data and for what purposes the data is being sent or received. A SDOH referral platform that is designed to support SDOH data exchange in compliance in with HIPAA, might nevertheless not be an option for an organization that operates a Part 2 program if the platform cannot support compliance with Part 2 requirements, such as displaying the prohibition on redisclosure notice and limiting disclosures of the Part 2 data only to authorized consent-recipients.

State health data privacy laws:

In addition to the complexities of data sharing in compliance with federal health data privacy laws in the United States, states have long had their own health data privacy laws that are often more restrictive than HIPAA. State laws applicable to health care providers and health plans may require one or more of the following requirements be met in order to permit the disclosure of individually identifiable health information to CBOs:

- The patient has signed a written consent form where federal law does not require consent;

⁹⁷ *Id.* § 2.11 (defining “Treating provider relationship”).

⁹⁸ *Id.* § 2.32(a).

⁹⁹ *Substance Abuse Confidentiality Regulations*, SAMHSA, <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs> (last updated Oct. 27, 2023) (explaining in FAQ #13 that logon or splash page notice “would not be sufficient notification regarding prohibitions on redisclosure since it would not accompany a specific disclosure”).

- The consent form meets requirements that are different and more stringent than HIPAA authorization requirements, such as specifically naming the individual or entity who may receive the information or specifying in greater detail the types of information that may be disclosed;
- The patient has been given the opportunity to opt out of (or opt into) persistent data sharing within a networked environment versus a single, one-to-one disclosure;
- The disclosing entity has transmitted a redisclosure notice or has satisfied other procedural requirements in connection with the disclosure of certain sensitive health information, such as HIV/AIDS-related information; and/or
- The state law prohibits the disclosure of certain information entirely, such as genetic testing information.¹⁰⁰

For example, a number of states with regional or statewide HIEs have passed legislation codifying a patient's right to consent to having their information shared through a HIE network.¹⁰¹ Whereas, the HIPAA Privacy rule *permits* covered health care providers to give patients the choice as to whether their health information may be disclosed through HIEs for certain purposes, including treatment, payment and health care operations, such consent is not required. Accordingly, the state of Arizona passed a Health Information Organization statute that imposes notice and consent requirements on health care providers that participate in the state designated HIE and that grants individuals in Arizona the right to opt-out of having their individually identifiable health information accessible through the HIE for clinical uses.¹⁰² In contrast to the opt-out model for consent in Arizona, other states like New York have imposed opt-in models whereby providers that participate in an HIE or the HIE itself must obtain patient consent *before* such patient's information may be accessed through the HIE network.¹⁰³ Given these different state requirements, a national SDOH solution written to support federal health data privacy standards may be sufficient for State A but may be insufficient for State B if the solution cannot support compliance with State B's particular requirements.

100 See generally Alexander Dworkowitz & Cindy Mann, *Data Sharing and the Law: Overcoming Healthcare Sector Barriers to Sharing Data on Social Determinants*, MANATT HEALTH (July 2020), https://sirenetwork.ucsf.edu/sites/default/files/2021-02/Data%20Sharing%20and%20the%20Law_July%202020_.pdf.

101 See CLINO VATIONS, STATE HIE CONSENT POLICIES: OPT-IN OR OPT-OUT, https://www.healthit.gov/sites/default/files/State%20HIE%20Opt-In%20vs%20Opt-Out%20Policy%20Research_09-30-16_Final.pdf (last updated Sept. 2016).

102 ARIZ. REV. STAT. ANN. §§ 36-3801–36-3809 (2023). For more information about the opt-out consent model applicable to the state designated HIE in Arizona, see *HIE Onboarding – Arizona*, CONTEXTURE, <https://contexture.org/hie-onboarding-arizona/> (last visited Dec. 5, 2023).

103 New York State HIEs (also called RHIOs) are regulated by the New York State Department of Health, in accordance with Article 10 of the New York Code of Rules and Regulations (NYCRR) Part 300. See HEALTHIX, COMPLIANCE WORK PLAN (Mar. 1, 2023), <https://www.healthix.org/wp-content/uploads/2023/02/Compliance-PlanFinal-2023.pdf>.

State Consumer Data Privacy Laws and other State and Federal Confidentiality Laws

Adding to the complexity is that CBOs—which range broadly from food banks and housing assistance organizations to legal aid and domestic violence shelters—may be subject to other state or federal confidentiality laws. This is particularly true for state and local entities that may wish to participate in a SDOH solution but may be subject to stringent state and local confidentiality laws with respect to when they may share personal information that they collect. For example, public schools are subject to the stringent confidentiality protections in the Family Educational Rights and Privacy Act and its implementing regulations (collectively, “FERPA”);¹⁰⁴ state public health authorities are often subject to restrictive state confidentiality laws on the use and disclosure of public health data;¹⁰⁵ and organizations that provide legal aid, serve children and/or support for those suffering from domestic violence and other forms of abuse/neglect are often subject to statutory, ethical, and common law duties of confidentiality.¹⁰⁶ SDOH platforms, networks and applications designed to support compliance with HIPAA only may be ill-equipped to address their needs.

Additionally, state after state is passing consumer data privacy laws that may apply to non-HIPAA regulated CBOs and impact their ability to participate or how they participate in SDOH data exchanges.¹⁰⁷ For example, Colorado has joined at least 10 other states in recent years that have enacted consumer data privacy laws. The Colorado Privacy Act and its implementing regulations (collectively, the “CPA”) went into effect on July 1, 2023, and applies to “controllers” that conduct business in Colorado or produce or deliver commercial products or services that are intentionally targeted to Colorado residents and that either (1) control or process “the personal data of [100,000] or more during a calendar year” or (2) derive revenue or receive “a discount on the price of goods or services from the sale of

104 20 U.S.C. § 1232g (2023) & 34 C.F.R. pt. 99 (2023) (collectively, “FERPA”).

105 *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-135 (confidentiality of identifying information in child immunization reporting system); *id.* § 36-664 (confidentiality of communicable disease related information); ARIZ. ADMIN. CODE § R9-4-504(C) (2023) (confidentiality of Birth Defects Monitoring Program data); CAL. HEALTH & SAFETY CODE § 102230(a) (2023) (confidentiality of vital statistics); *id.* § 103885 (2023) (confidentiality of statewide cancer reporting system data); COLO. REV. STAT. ANN. § 25-4-1905 (2023) (confidentiality of Gulf War Syndrome Registry data).

106 *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-897 (confidentiality of personally identifiable child care group home information relating to a child, parent, or guardian); ARIZ. ADMIN. CODE § R21-6-322 (confidentiality of foster child’s personally identifiable information); ARIZ. REV. STAT. ANN. § 36-3005 (requiring domestic violence service provider to “adhere to statewide service standards for domestic violence programs that are approved by the department of economic security in collaboration with a state coalition against domestic violence”); AZ COALITION TO END SEXUAL AND DOMESTIC VIOLENCE, ARIZONA SERVICE STANDARDS FOR DOMESTIC VIOLENCE SERVICE PROVIDERS, <https://www.acesdv.org/wp-content/uploads/2022/02/Final-AZ-DV-Service-Standards-2021.pdf> (requiring “confidentiality of any information potentially identifying individuals seeking, receiving or denied services”); CAL. GOV’T CODE §§ 6205–6211 (2023) (Address Confidentiality for Victims of Domestic Violence, Sexual Assault, and Stalking).

107 *See, e.g.*, Andrew Folks, *US State Privacy Legislation Tracker*, IAPP, <https://iapp.org/resources/article/us-state-privacy-legislation-tracker/> (last updated Nov. 17, 2023).

personal data and process[] or control[] the personal data of [25,000] consumers or more.”¹⁰⁸ Unlike other state consumer data privacy laws, the CPA does not exempt non-profit organizations and may not have exceptions that fully cover the use and disclosure of personal data on SDOH data exchanges and networks, if such data is not HIPAA-regulated or done on behalf of Colorado state or local entities. Thus, CBOs may have to comply with CPA requirements with respect to their downstream participation in SDOH data exchanges, such as providing adequate notice of this activity, flowing down CPA requirements to the technology companies that provide the service, meeting individual data rights, and so on. Similar issues may impact CBOs in other states with similar consumer data privacy laws.

Consequently, individuals and entities desiring to offer SDOH solutions—particularly referral platforms and networks—and those desiring to access, exchange, and use information that is accessible through such services must carefully consider not only whether this can be done in compliance with the health data privacy laws discussed in State Consumer Data Privacy Laws and Other State and Federal Confidentiality Laws on page 28, but other state and federal confidentiality laws that might apply to the CBOs who will participate. This can be a daunting task, particularly for CBOs that may have little to no experience with data sharing arrangements and that might lack the resources to engage with legal counsel and technology specialists to understand whether they can participate in a SDOH solution based on the laws that apply to them and how the technology will work.

Consumer Communication Laws and Issues

While beyond the scope of this Article, in addition to the confidentiality laws discussed above, there are other various laws, regulations, or requirements that might impact outreach efforts with populations in need. Such laws or requirements include, but are not limited to, the following:

- **The Controlling Assault of Non-Solicited Pornography and Marketing Act of 2003 (CAN-SPAM).** CAN-SPAM established national standards for the sending of commercial e-mail and was enacted in response to a growing number of complaints over spam e-mails.¹⁰⁹ If the message is subject to CAN-SPAM, various requirements apply, such as using accurate subject and to/from lines, including valid physical addresses in the communication, explaining clearly and conspicuously how recipients can opt-out, and requiring opt-out requests to be promptly addressed.¹¹⁰

108 COLO. REV. STAT. ANN. § 6-1-1304(1).

109 See 15 U.S.C. §§ 7701–7713.

110 *CAN-SPAM Act: A Compliance Guide for Business*, FED. TRADE COMM’N (Aug. 2023), <https://www.ftc.gov/business-guidance/resources/can-spam-act-compliance-guide-business>.

- **The Telephone Consumer Protection Act of 1991 (TCPA).** The TCPA was enacted to restrict unsolicited and automated calls, primarily associated with telemarketing, including the use of artificial or prerecorded voice messages.¹¹¹ The TCPA, however, also applies to short message service (SMS) text messages, which is a significant tool to reach and communicate with various populations. Failure to comply with the TCPA can result in significant penalties or class action exposure. While the TCPA's applicability was recently limited by the U.S. Supreme Court's decision in *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163 (2021), a significant body of law and regulations surround the TCPA and should be considered in developing an outreach strategy or when leveraging certain technologies. It is also important to note that various states have adopted, or are currently considering, mini-TCPA corollaries to close perceived gaps because of *Duguid*, and further federal action is anticipated as well.
- **CTIA Carrier Guidelines.** The CTIA is a trade association that represents all sectors of wireless communications, cellular, and personal communications services.¹¹² As part of their work in the wireless industry, the CTIA has established guidelines surrounding the use of SMS text messages.¹¹³ Unlike the TCPA, the guidelines do not carry the same legal risk as the TCPA. However, the CTIA guidelines may require a heightened level of consent for certain messages, and carriers reserve the right to block senders, filter messages, and pass on fines that violate the guidelines.¹¹⁴

Technology Challenges

Against this complex legal landscape, it is easy to perceive how designing the technology to satisfy differing legal requirements is challenging. Compounding the technology challenge for SDOH solutions is that EHRs and technology more generally has developed such that the ability to segment and suppress data is done at a document level (*i.e.*, assessments, clinical notes, lab results, *etc.*); and not based on the identity of the individual, facility or organization that has supplied the information.

Federal and state laws, moreover, do not generally require health care providers, payers, and CBOs to identify or tag as particularly sensitive or uniquely confidential the data that they enter about individuals into EHRs or other technology systems at the point of data entry. This has created a considerable gap between how technology is designed and how privacy laws are written because the privacy laws—*i.e.*, to whom they apply and what they protect—is based on who is collecting or creating the data and not on how that data is stored/expressed in a technology system's data architecture (*see, e.g.*, Health Data Privacy Laws on page 21).

111 47 U.S.C. § 227; *see also* Barr v. Am. Ass'n of Pol. Consultants, 140 S. Ct. 2335 (2020) (finding non-relevant provision of TCPA unconstitutional on other grounds).

112 *Our Mission*, CTIA, <https://www.ctia.org/about-ctia/our-mission> (last visited Dec. 5, 2023).

113 *See generally* CTIA, MESSAGING PRINCIPLES AND BEST PRACTICES (July 2019), <https://api.ctia.org/wp-content/uploads/2019/07/190719-CTIA-Messaging-Principles-and-Best-Practices-FINAL.pdf>.

114 *Id.*

Additionally, how a technology vendor, health care provider, or the law approaches particularly sensitive health information might not reflect the patient's preferences on what is particularly sensitive to them. For example, a patient who desires that their substance use disorder information not be shared with anyone likely does not base that desire on whether that piece of information came from their MAT clinic (*e.g.*, a Part 2 program) or the general hospital that treated them for an overdose (*e.g.*, not a Part 2 program). And these gaps between the technology, the laws, and patient expectations have real implications on whether SDOH solutions are adopted and how they are implemented.

For example, Health System A may desire to participate in a private SDOH referral platform and exchange that supports the exchange of certain assessments and other documents between and among its provider, payer, and CBO participants in compliance with HIPAA requirements and using an integrated solution that automatically pulls/pushes the assessments and other documents from/to the EHR on matched patients. The technology vendor that operates the SDOH solution disclaims compliance with state or federal data laws other than HIPAA, expressly prohibits its participants from sharing data that is subject to laws more stringent than HIPAA and places the burden of compliance with such laws solely on its participants. Health System A operates a couple of Part 2 programs and uses a single EHR to support all of its facilities. Health System A's EHR might be able to suppress all "assessments and plans of treatment" from being released from the EHR to the private SDOH solution but cannot suppress only those "assessments and plans of treatment" that were created by the health system's Part 2 program providers. Moreover, there is not functionality within the EHR that would allow Health System A's Part 2 program providers to tag the "assessments and plans of treatment" they create as "sensitive" and subject to suppression. As a result, Health System A's options are to not participate in the private SDOH solution or "turn off" the release of all "assessments and plans of treatment," thereby diminishing the utility of the solution.

Other technical challenges include the following:

- The SDOH solution may lack the technical functionality for supporting consent management and patient privacy restrictions in compliance with applicable federal and state laws. For example, the SDOH solution might not have a consent module that allows for appropriate individuals to activate and deactivate an individual's consent to SDOH data exchange, or it might not have the ability to implement the individual's consent preferences at the level of granularity desired or expected by individuals or participants. For example, a SDOH solution might be able to implement an "all or nothing" approach to access and exchange based on an uploaded consent, but might not be capable of only "turning on or off" access based on participant identity (*e.g.*, consent for Participant A only or consent for all Participants except for Participant B) or the type of information being exchanged (*e.g.*, consent to share only physical health information but not behavioral health).

- The SDOH solution may be interoperable with a provider’s EHRs, but inoperable with a CBO’s technology because of the lack of standardization for SDOH transactions to and from CBOs. Notwithstanding the significant steps toward data standardization for SDOH use cases that have occurred over the last five years (see Other SDOH Data Policies and Initiatives on page 15), these developments have occurred almost exclusively in the health care space and have been advanced through ONC’s Certification Program, which only applies to certified health IT. In order for SDOH solutions to be successfully integrated within the CBO workflows, the same level of effort and financial investment is needed for CBOs that are not using technology certified by ONC and which often lack the resources necessary to procure or upgrade their technology.

Culture Shift

Finally, the human and cultural factors in successful implementation of a SDOH solution should not be overlooked. For decades, the posture in the United States to sharing patient health information has been one of paternal protectionism—that is, looking to health care providers and health plans to act as the dutiful parent responsible for safeguarding and protecting the confidentiality of health information or face significant penalties for the unauthorized use or disclosure of that information. Given the complexity of federal and state health data laws, it is not surprising that over time the industry’s approach has been to not share health information if there is any uncertainty as to whether doing so would be appropriate, such as whether it is appropriate to share health information with a CBO that is not regulated by HIPAA. Moreover, the idea of electronic referral platforms and digital data sharing networks is entirely new to many CBOs, many of which have never participated in data sharing arrangements. Similar to the early days of clinical health information exchange, many CBOs are uncertain whether it is legal or appropriate for them to participate in such exchanges.

HOW TO SOLVE THE PUZZLE: SOLUTIONS FROM THE LEGAL PERSPECTIVE

In response to the various privacy laws and issues raised above, what are stakeholders to do? In this section, we discuss some best practices for putting the puzzle together within existing privacy laws and provide a few examples of how stakeholders are seeking to change the laws to achieve a better picture of whole person care.

Best Practices: Working Within Existing Privacy Laws

Currently, stakeholders interested in implementing SDOH solutions to achieve a picture of whole person care are tasked with putting together a complex jigsaw puzzle under existing federal, state, and local privacy laws. For some, the puzzle may be less legally complex, *e.g.*, a treating health care provider desires to fax a patient’s name and contact information to a local

housing service provider pursuant to HIPAA's treatment exception. For others, more in-depth analysis is necessary. For instance, what if that treating provider wants to use a digital referral platform to send the housing referral, and that platform is networked such that any participant in the network that has a relationship with the patient—such as the patient's payer, other CBOs or governmental agencies—will see that referral and also have access to any assessments and screenings the provider completed on the platform? What if that platform also enables the referring provider and receiving housing authority to send text messages and emails to the patient?

The following are some best practices/considerations to fit these pieces together:

- **Best Practice #1: Understand Your Obligations and How the SDOH Solution Works.** Organizations interested in participating in a SDOH solution should work with experienced legal counsel, compliance personnel, and technology staff to take inventory of their existing or potential privacy, security, and interoperability obligations relating to their data and their SDOH goals. This involves understanding both the laws that might apply to the data the organization will share through the SDOH solutions *and* what laws might apply to the organization if they receive information through the solution. For example, if the organization will receive Part 2 data from Part 2 programs that participate in a SDOH referral network, the organization should understand its direct obligations under Part 2 with respect to the Part 2 data. To fully understand legal obligations, moreover, organizations must also know how the SDOH solution will work from a technological standpoint, under what legal framework(s) it will operate, and whether the organization must agree to flow down requirements in order to support those frameworks, as well as what patient-facing communications it will support.
- **Best Practice #2: Consent/Authorization.** If an opportunity exists to obtain some form of documented written or verbal consent or authorization, try to obtain it. Given the current confusion in this space, obtaining broad consent or authorization from individuals will cure many ills in overcoming the industry haze—if it is not already legally required. For example, a CBO working directly with providers or health plans may seek to leverage a HIPAA authorization to make it easier to obtain PHI from those covered entities because of the certainty it provides with respect to how much PHI may be shared and for what purposes. Similarly, leveraging an authorization process for a multi-stakeholder, closed loop referral system may also lessen compliance risks by taking the data outside of HIPAA's purview. Finally, obtaining the patient's consent (opt in) to the SDOH solution, even if might not be legally required, is a best practice to ensure alignment with an individual on using and disclosing their information and to reduce complaints to regulators. And such consents (when not legally required) can often be combined with other important consents, such as the individual's informed consent to receive unencrypted text message notifications or to receive health-related email communications. Indeed, many SDOH

solutions offered by technology vendors expressly require platform users to obtain patient consent to their privacy and communication practices as a licensing condition to sending referrals or exchanging SDOH data on the platform. Individuals and organizations subject to the federal Information Blocking Rule (IBR) can minimize IBR risks associated with requiring patient consent when it is not legally required by utilizing IBR safe harbor protections for honoring a patient's privacy requests and best security practices in the health care industry.¹¹⁵

- Best Practice #3: Evaluate and Document Exceptions to Consent/Authorization.** Existing privacy exceptions to consent/authorization requirements, such as HIPAA's treatment and health care operations exceptions, should also be considered (and documented) when it is administratively burdensome or simply not possible to obtain some level of written or oral consent from the individual. For example, a primary care provider that doesn't provide health care services subject to privacy laws more stringent than HIPAA may internally decide to only use a SDOH solution to send one-to-one referrals to CBOs for treatment purposes and to not utilize any networked functionality or patient-facing communications. In this case, it might not be necessary for the provider to obtain any consent from their patients beyond the patients' written acknowledgment of receipt of the provider's HIPAA Notice of Privacy Practices that allows for treatment, payment and health care operations activities. Organizations should consider specifying in their health information policies and procedures (and their routine HIPAA and IBR training) when it is permissible to share PHI (and how much PHI) in connection with a SDOH solution or initiative.
- Best Practice #4: SDOH Training, Templates, and Toolkits.** Case managers, care coordination members and other personnel/staff involved in SDOH initiatives should receive targeted training on applicable privacy laws and the compliant pathways to use and disclose information for SDOH purposes. CBOs and similar organizations should also receive general education on these laws to help team members navigate the health care space. Templates, tool kits, and check lists are also incredibly helpful to navigate these issues.
- Best Practice #5: Data Segregation/Suppression.** If an organization provides a wide range of health care or community-based services and are subject to federal or state privacy laws more stringent than HIPAA (*e.g.*, HIV/AIDS, behavioral health, substance use disorders, reproductive health, *etc.*), the organization could try to segregate functions, information systems, and related data to ensure information subject to such laws is not impermissibly used or disclosed or comingled with data subject to less protection to support SDOH initiatives. As noted above, technological limitations with EHR technology may make this a difficult task. However, if feasible,

115 See generally 42 U.S.C. § 300jj-52 and 45 C.F.R. pt. 171 (2023).

segregation should be considered. In fact, some SDOH solutions may offer sensitive data identification and suppression as an additional product or service offering. Indeed, data suppression software is available that can search for CPT/ICD codes and free text and suppress information associated with sensitive diagnoses and conditions. Such software, however, does not often run in real time and may be over- or under-inclusive of what is suppressed.

Proposed Changes to Privacy Laws to Advance SDOH Efforts

While it is possible to implement SDOH solutions within existing laws, there are opportunities to increase their adoption and success by changing the laws. As discussed below, regulators, legislators, and other stakeholders are currently seeking to change the laws to advance SDOH initiatives.

HIPAA

In January 2021, HHS released a Notice of Proposed Rulemaking and suggested certain changes, among others, to the HIPAA Privacy Rule that will have a positive impact for stakeholders in the SDOH space, if implemented.¹¹⁶ While proposing clearer pathways to support certain uses and disclosures to CBOs and social service agencies, HHS also reinforced the existing treatment and health care operations pathways to support case management and care coordination activities.

First, HHS addressed confusion from covered entity health plans surrounding the permissible scope of the health care operations exception to support case management and care coordination activities that would be relevant for SDOH initiatives. For some relevant background, health plans do not conduct “treatment” activities and thus cannot rely on HIPAA’s treatment exception to the authorization requirement, leaving primarily only the “health care operations” exception to use or disclose PHI for those functions.¹¹⁷ However, the definition of “health care operations” is defined as “population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination . . . and related functions that do not include treatment.”¹¹⁸ Because of the “population-based” modifier in the definition, certain covered entity health plans were taking the position that individual-focused case management and care coordination activities were not permitted by the exception and that only broader community- or population-based activities were permissible.¹¹⁹ It is important to note that this is not an interpretation that HHS

116 See generally Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6,446 (proposed Jan. 21, 2021) (to be codified at 45 C.F.R. pts. 160 & 164).

117 *Id.* at 6,472.

118 45 C.F.R. § 164.501 (“Health care operations”).

119 Proposed Modifications to the HIPAA Privacy Rule, 86 Fed. Reg. at 6,472.

has supported in the past and that specific examples in guidance in the preamble to the 2000 Privacy Rule demonstrate HHS rejecting such a narrow interpretation.¹²⁰ Even so, and as recognized by HHS, it is a fair interpretation based on the plain language of the definition. As a result, HHS proposes to clarify the definition of health care operations in the regulations “to encompass all care coordination and case management by health plans, whether individual-level or population-based.”¹²¹

Second, HHS proposed an express exception to the minimum necessary standard “for disclosures to, or requests by, a health plan or covered health care provider” for care coordination and case management activities.¹²² As noted earlier, uses and disclosures related to treatment are not subject to the minimum necessary requirement like those made for health care operations purposes.¹²³ Thus, because health plans can only rely on the health care operations exception, HHS noted that the current regulations “impose[] greater restrictions on disclosures to and requests by health plans than on disclosures to and requests by covered health care providers” for case management and care coordination activities related to an individual.¹²⁴ The proposal would put health plans and covered providers on the same playing field for case management and care coordination functions. Importantly, as proposed, the exception would only apply to uses and disclosures in support of those activities at an individual level; the minimum necessary standard would continue to apply to disclosures to non-covered entities, such as social service agencies or CBOs, however.¹²⁵

Finally, HHS responded to stakeholder confusion and reinforced and clarified the existing treatment and health care operations pathways to disclose information to CBOs, social service agencies, *etc.* for case management and care coordination purposes while also proposing a new modification to the regulations to remove doubt. HHS specifically raised this issue because it had learned that many covered entities were making disclosures to CBOs only after obtaining a valid authorization or that some covered entities were never disclosing PHI to these health-related partners—even when a treating provider specified a certain service as part of a treatment plan.¹²⁶ Accordingly, HHS reinforced the existing treatment and health care operations pathways and existing guidance, and to further remove doubt, HHS proposes to modify the rules to create a new exception for individual-level care coordination and case management activities that would expressly permit disclosures of PHI—without an authoriza-

120 *Id.*

121 *Id.*

122 *Id.* at 6,474.

123 *Id.* at 6,473.

124 *Id.*

125 *Id.*

126 *Id.* at 6475.

tion or consent—to social service agencies and CBOs that provide health-related services to individuals.¹²⁷ HHS explained its proposal as follows:

This express permission would allow a covered entity to disclose PHI to these third party entities that provide or coordinate ancillary and other health-related services when the covered entity determines that the disclosure is needed to provide health-related services to specific individuals for individual-level care coordination and case management activities that constitute treatment or health care operations, as applicable. For example, a covered entity could disclose the PHI of a senior individual experiencing chronic illness to a senior center attended by the individual to check on his or her health periodically, and to ask the senior center to give reminders about effective disease self-management.¹²⁸

HHS further noted that “the third party entities receiving PHI under this proposed permission would not be covered entities and thus, the PHI disclosed to them would no longer be protected by the HIPAA Rules.”¹²⁹ In supporting an exception without any individual authorization or consent requirement, HHS also explained that “the limitation to individual-level activities will ensure that the disclosures made under this permission would be akin to disclosures for treatment, which individuals expect to occur without their needing to provide an authorization or consent.”¹³⁰

Ultimately, these new proposals, if implemented, will provide greater clarity and flexibility for covered entities seeking to work with CBOs and social service agencies to address SDOH issues.

Part 2

HHS has also proposed significant changes to the Part 2 regulations. In 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act of 2020 (the “CARES Act”),¹³¹ which included provisions to align Part 2’s breach requirements, enforcement structure, and stringent privacy protections with HIPAA.¹³² It did not, however, remove the requirement

127 *Id.* at 6475–76

128 *Id.* at 6,476.

129 *Id.*

130 *Id.* at 6,477.

131 Pub. L. No. 116-136, 134 Stat. 281 (2020) (codified as amended in 42 U.S.C. § 290dd-2 and other scattered sections of the United States Code); for a more detailed summary of Section 3221 of the CARES Act, please read Melissa Soliz & Kristen Rosati, *The CARES Act: Sweeping Changes to Substance Use Disorder Privacy Law (42 U.S.C. § 290dd-2)* (Mar. 30, 2020); technical corrections made Apr. 2, 2020, <https://www.cblawyers.com/wp-content/uploads/2020/04/The-CARES-Act-Sweeping-Changes-to-Substance-Use-Disorder-Privacy-Law-42-USC-290dd-2.pdf>.

132 “HIPAA” collectively refers to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended. *See generally* 45 C.F.R. pts. 160 & 164 (2023).

that patients consent to the use and disclosure of their Part 2 data for non-emergency treatment, payment and health care operations. The initial consent requirement remains. On December 2, 2022, HHS published its notice of proposed rulemaking to revise the Part 2 regulations to implement the CARES Act amendments (the “2022 Part 2 Proposed Rule”).¹³³ HHS anticipated releasing the final rule in October 2023; however, as of December 3, 2023, the final rule has not been released.¹³⁴

If finalized as proposed, the 2022 Part 2 Proposed Rule may lower the barrier to participation of Part 2 programs in SDOH solutions and the sharing of Part 2 data in two ways. First, HHS proposed to align the Part 2 consent form requirements with HIPAA authorization requirements.¹³⁵ This would be beneficial to SDOH solutions that utilize a HIPAA authorization approach to sharing health information with third parties, like CBOs. However, the Part 2 consent form requirements would still not be identical to the HIPAA authorization elements. For example, if Part 2 data is being exchanged through an “intermediary” in a networked environment, the consent that is used must still name the intermediary that is facilitating exchange and the ultimate recipients of the Part 2 data must be limited to those individuals or entities that are either specifically named on the consent form or, if a general designation consent is used, have a “treating provider relationship” with the patient.¹³⁶ HHS proposed to keep the substantive definition of “treating provider relationship” the same (subject to some technical changes)¹³⁷ and to define an “intermediary” as “a person who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient.”¹³⁸ HHS explained that this is a functional definition, which would include a “health information exchange, a research institution that is providing treatment, an accountable care organization, or a care management organization”¹³⁹ or “an electronic health record vendor that enables entities at two different health systems to share records”¹⁴⁰ Given these definitions, this proposed change—unless further modified before finalization—may have limited utility or impact on how SDOH solutions are implemented if those solutions are being implemented through an organization that functions as an “intermediary.”

Second, HHS proposed to permit HIPAA covered entities, HIPAA business associates, and Part 2 programs that receive Part 2 data pursuant to a patient’s consent to use and disclose the Part 2 data for treatment, payment and health care operations purposes (collectively, “TPO”), to reuse and redisclose that Part 2 data for *any purpose permitted by HIPAA*, except

133 Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74,216 (proposed Dec. 2, 2022) (to be codified at 42 C.F.R. pt. 2 & 45 C.F.R. pt. 164).

134 RIN: 0945-AA16, REGINFO.GOV, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0945-AA16> (last visited Dec. 5, 2023).

135 Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. at 74,280–81.

136 *Id.* at 74,281.

137 *Id.* at 74,275.

138 *Id.* at 74,274–75.

139 *Id.* at 74,229.

140 *Id.*

for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.¹⁴¹ It is unclear, however, how this broad permission will work given HHS' proposal to limit the downstream redisclosure of Part 2 data through intermediary organizations, as described above. Presumably, HIPAA business associates that function as intermediaries and use a general designation consent will still be required to limit redisclosures to only those end recipients who meet the definition of having a "treating provider relationship" with the patient. Thus, depending on when this proposed change is finalized, it may also have limited impact on how some SDOH solutions are implemented.

The 2022 Part 2 Proposed Rule would also not remove the requirement that each disclosure of Part 2 data pursuant to a patient's consent, including a TPO consent, be accompanied by the prohibition on redisclosure notice. HHS proposed to retain that requirement but rebrand it as a "notice to accompany disclosure" and to modify the language of the long-form notice to better reflect when downstream uses or disclosures are permitted by the recipient.¹⁴²

Although the proposed changes have the potential to make a positive impact toward the inclusion of those suffering from substance use disorders in SDOH solutions, the proposed changes to the Part 2 breach and enforcement structure may discourage their inclusion. Prior to the CARES Act amendment and 2022 Part 2 Proposed Rule, Part 2 programs that did not operate as HIPAA covered entities were not subject to the HIPAA breach reporting requirements. Under the proposed changes, they will be subject to these requirements,¹⁴³ thereby increasing the risk of participating in certain SDOH solutions where the participation may materially increase the risk of the Part 2 program data supplier being involved in a reportable data breach. Additionally, the proposed changes would shift enforcement from criminal penalties imposed by the Department of Justice (DOJ)—which historically has not enforced Part 2¹⁴⁴—to HHS, which would enforce Part 2 under the same civil and criminal enforcement structure used for HIPAA.¹⁴⁵ For example, HHS could impose civil penalties against any person for Part 2 violations ranging from \$100 to \$50,000 per violation with an annual cap of \$25,000 to \$1.5 million (not adjusted for inflation), depending on the level of intent involved.¹⁴⁶ Thus, the specter of HHS enforcement of Part 2 may have a chilling effect on the availability of SDOH solutions that permit Part 2 program participation or data sharing, as well as participation in those solutions.

141 *Id.* at 74,281–82.

142 *Id.* at 74,241, 74,281.

143 *Id.* at 74,277; *see also* Notification in the Case of Breach of Unsecured Protected Health Information, 45 C.F.R. pt. 164, subpt. D (2023).

144 Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. at 74,225, n.104.

145 *Id.* at 74,274.

146 *See id.* (proposing amendment to 42 C.F.R. § 2.3); *see also id.*; 42 U.S.C. §§ 1320d-5, -6 (2023); Title 18 of the U.S. Code.

Federal Privacy Law Preemption and Model State Laws

Another interesting development is the growing cry for a single, uniform privacy law across all sectors of the U.S. economy, including health care. The sector-specific approach to data privacy in the United States, the lack of an omnibus federal consumer privacy law, and the growing proliferation of state-level consumer data privacy laws have collectively created a complex and burdensome landscape for businesses, including CBOs, that handle SDOH data and other consumer information and wish to share such information to support their customers' health needs. The current, patchwork regulatory landscape has prompted renewed efforts at the federal level to enact federal consumer privacy legislation with preemption provisions that would establish a more streamlined and coherent privacy framework in the U.S.¹⁴⁷

The U.S. Congress made bipartisan progress in the House on comprehensive federal privacy legislation in 2022, advancing the proposed H.R. 8152, the American Data Privacy and Protection Act,¹⁴⁸ out of the House Energy and Commerce Committee.¹⁴⁹ Ultimately, however, questions over issues including state law preemption (*i.e.*, the degree to which a federal consumer privacy protection law can override state laws) prevented the legislation from advancing to a full floor vote.¹⁵⁰ Proponents of an omnibus federal consumer privacy law that would preempt state level regulations assert that it would end the current patchwork of laws that have led to inconsistent protections for consumers across state lines and avoid the compliance related challenges of the current environment.¹⁵¹ Advocates further argue that a single consumer privacy framework would be more efficiently integrated into business operations and would ultimately foster greater consumer trust by imposing uniform, consistent and robust safeguards regardless of the state in which a consumer resides.¹⁵² There is ongoing debate on whether federal privacy legislation should allow for stronger state privacy frameworks or whether it should prevent states from having their own frameworks at all.¹⁵³

147 See, e.g., Stacey Gray, *Long Overdue: Comprehensive Federal Privacy Law*, FUTURE PRIV. F. (Nov. 15, 2018), <https://fpf.org/blog/fpf-comments-on-a-national-baseline-consumer-privacy-law/>; Peter Swire, *US federal privacy preemption part 1: History of federal preemption of stricter state laws*, IAPP (Jan. 9, 2019), <https://iapp.org/news/a/us-federal-privacy-preemption-part-1-history-of-federal-preemption-of-stricter-state-laws/>.

148 American Data Privacy and Protection Act, H.R. 8152, 117th Cong. (2022), <https://www.congress.gov/117/bills/hr8152/BILLS-117hr8152rh.pdf> (introduced on June 21, 2022 by Representative Pallone (D-NJ)).

149 See Joseph Duball, *U.S. House lawmakers keep federal privacy legislation top of mind*, IAPP (Mar. 1, 2023), <https://iapp.org/news/a/us-house-lawmakers-keep-federal-privacy-legislation-top-of-mind/>.

150 *Cal. Privacy Prot. Agency Releases Letter Opposing H.R. 8152, the Am. Data Privacy and Prot. Act*, BUSINESS WIRE (Aug. 16, 2022, 11:29 AM), <https://www.businesswire.com/news/home/20220816005319/en/California-Privacy-Protection-Agency-Releases-Letter-Opposing-H.R.-8152-the-American-Data-Privacy-and-Protection-Act>.

151 See *Long Overdue: Comprehensive Federal Privacy Law*, *supra* note 147.

152 *Id.*

153 Lauren Zabierek et al., *Preemption in Fed. Data Sec. and Privacy Legis.*, BELFER CTR FOR SCI. AND INT'L AFFS., HARVARD KENNEDY SCH. (June 14, 2022), <https://www.belfercenter.org/publication/preemption-federal-data-security-and-privacy-legislation#:~:text=Preemption%20is%20the%20ability%20of,in%20favor%20of%20federal%20law.>

Outside of the consumer privacy context, a number of legislative efforts have surfaced in recent years designed to promote greater coordination between the health care sector and the social services sector. For example, the Leveraging Integrated Networks in Communities (LINC) to Address Social Needs Act (S. 509) was introduced in 2021 and would award grants to states to develop or enhance collaboration between health care organizations and social service sectors. Co-sponsored by Senators Dan Sullivan (R-AK) and Chris Murphy (D-CT), the bill authorized \$150 million in funding for states to be awarded by HHS to develop or enhance cross-sector data sharing capabilities and public-private partnerships to leverage technology-based community service interventions to support health-related needs of individuals. Proponents of the legislation, which include technology vendors that supply closed-loop referral platforms, cite work that is currently underway in states like North Carolina¹⁵⁴ or Arizona¹⁵⁵ to support the proposed approach.

There are also efforts moving in parallel at the state level to promote consistency in state data sharing laws. For example, the American Legislative Exchange Council has endorsed model state policy that would establish a “health data utility” in each state to support state Medicaid programs and to facilitate the exchange of information across the medical, public health and social services sectors.¹⁵⁶ A state health data utility is defined in the model policy as a public-private partnership organized to “achieve better patient outcomes, improve the overall health and wellbeing of the people of the state[, and] reduce the cost of health care services by creating a more seamless, transparent, and modernized approach to sharing health information.”¹⁵⁷ The model state policy would require all entities engaged in the sharing of SDOH information to be participants in the health data utility and to share data in accordance with federal law and policies adopted by a state health information technology board that would be organized pursuant to the model policy.

154 The North Carolina Department of Health and Human Services has entered into a public-private partnership with United Way, private foundations, and tech vendors to launch the NCCARE360 initiative, which connects CBOs and the state’s health care system. NCCARE360 includes access to a statewide resource directory and call center and a community data repository that integrates multiple resource directories across the state and allows data sharing, and a shared technology platform that enables health and human services providers, CBOs, and others to send and receive electronic referrals, communicate and track patient outcomes. See, Zachary Wortman et al., *Buying Health for N. Carolinians: Addressing Nonmedical Drivers of Health at Scale*, 39 HEALTH AFFAIRS 4 (April 2020), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01583?journalCode=hlthaff>.

155 As a component of the Arizona Health Care Cost Containment System’s (AHCCCS) Whole Person Care Initiative (WPCI), AHCCCS has partnered with the statewide health information exchange in Arizona to implement a statewide Closed Loop Referral System, <https://www.azahcccs.gov/AHCCCS/Initiatives/AHCCCSWPCI/>. The CommunityCares system incorporates a community resource inventory and a closed loop referral platform that is designed to allow health care and community service providers to connect on a single statewide technology platform to improve and track the referral process between health care providers and social services and to facilitate screening for social risk factors. See *Statewide Closed-Loop Referral System: Cmty. Cares*, *supra* note 61.

156 *Model Policy: Statewide Health Data Util. Act*, AM. LEGIS. EXCH. COUNCIL (DEC. 23, 2022), <https://alec.org/model-policy/statewide-health-data-utility-act/>.

157 *Id.*

The Health Data Utility concept to promote the exchange of clinical and SDOH data has been gaining traction in other contexts as well. In March 2023, Civitas Networks for Health, a membership organization for HIEs, published a Health Data Utility Framework designed to guide states, regions, HIEs, and community partners through the evolution from HIE to a health data utility.¹⁵⁸

Advancement of Data Policies and Technology Standards

This puzzle cannot be solved solely at the legal or policy level. In order for SDOH solutions to work, there must be data and technical standardization in both the health care space and among CBOs. As discussed in Other SDOH Data Policies and Initiatives on page 15, there are a number of public/private collaborations operating in the health care space. These efforts can be advanced through more participation by interested stakeholders and by engaging with, and investing in, CBOs.

CONCLUSION

Harnessing the potential of health data to identify and close the SDOH gap and achieve health equity is akin to solving a complex jigsaw puzzle with numerous interlocking pieces. Just as a master puzzler meticulously arranges each piece to create a coherent and meaningful image, stakeholders must collaboratively navigate the intricate patchwork of federal and state laws to ensure compliance while maximizing the transformative power of data-driven solutions. By carefully assembling the pieces of this intricate puzzle, stakeholders can unlock the insights needed to design targeted interventions, allocate resources more effectively, and tailor health care services to achieve the designed picture of health equity in the United States.

158 See *Health Data Util. Framework – A Guide to Implementation*, CIVITAS NETWORKS FOR HEALTH, <https://www.civitasforhealth.org/hduframework/> (last visited Dec. 5, 2023).

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