September 9, 2024

**VIA ELECTRONIC SUBMISSION**

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1809-P
Baltimore, MD 21244-1850

**Re CMS-1809-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; etc.**

Dear Administrator Brooks-LaSure:

Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding CMS-1809-P (89 FR 49186, July 22, 2024) Section XIV. Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs and Section XVII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The ASC QC is a non-profit organization dedicated to advancing high quality, patient-centered care in ambulatory surgery centers (ASCs) through a collaborative membership of ASC stakeholders. Participants include leaders from ASC management companies, industry associations, professional physician and nursing associations, accreditation organizations and information technology companies (please see Appendix A to this letter for a complete listing). Collectively, these organizations represent over 2,200 ASCs.

The ASC QC's strong commitment to quality is reflected in our work to enable meaningful quality measurement in ASCs, including our development of ASC quality measures and our quarterly posting of publicly reported ASC quality data[1], all of which is made possible through the voluntary efforts of our members.

We appreciate the efforts of CMS staff to improve the ASC Quality Reporting (ASCQR) Program and are pleased to have this opportunity to offer insights and recommendations regarding the agency's proposals for the ASCQR Program and related Program details.

## I. CMS Proposals Surrounding Health Equity

[1] ASC Quality Collaboration Quality Report. Available at: https://ascquality.org/benchmarking/.

Recent proposals for the various CMS quality reporting programs have focused on health equity. The root causes of disparities in health equity in the United States include long-standing inequalities in economic, social, political, and environmental circumstances. These inequalities are reflected in disparities in income and wealth, education, employment, housing, transportation, and public safety. These factors in turn impact individual health and well-being.

These long-standing inequities in the structure of our society are very important yet reach well beyond the ability of healthcare professionals to resolve, as CMS has acknowledged: "[m]any of the biggest drivers of health and health care costs are beyond the scope of health care alone."[2] The National Academies of Sciences, Engineering, and Medicine has recognized "there is not a robust evidence base from which to draw solutions for implicit bias and its effects" and that more evidence-based solutions are needed to address societal conditions that can impact individual health.[3] The research needed to guide scientifically sound solutions for surgical practice is still in the nascent stage.

We look forward to the time when evidence-based practices become available to direct efforts to secure equitable outcomes in outpatient surgical and procedural care. In the interim, we believe ASCs should participate in efforts to address health equity; its importance is unquestioned. Providing high quality care to all individuals is a defining characteristic of a well-performing ASC. Each center has a role to play by not only ensuring their processes and outcomes of care are equitable, but also by providing care consistent with individual needs and preferences, and by striving to provide an excellent patient experience for all. Where disparities exist, they absolutely must be addressed as a matter of priority.

## II. Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure

The Screening for SDOH measure proposed for the ASCQR Program has been adopted into and proposed for multiple additional settings, including the Hospital Outpatient Quality Reporting (HOQR) Program. In its rationale for the measure, CMS stated its goal is to implement the measure across its quality reporting programs in support of its strategic vision to achieve equity across the health care system. With respect to the ASCQR Program, the agency believes it is important to capture patients' SDOH, believing that doing so "may impact surgical/outpatient care experience and recovery" and "further a facility's understanding of populations served and provide an opportunity to connect patients more effectively with specialized care and/or resources." [4]

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[2] Centers for Medicare & Medicaid Services. Accountable Health Communities (AHC) Model Fact Sheet. 2016. Available at: https://www.cms.gov/newsroom/fact-sheets/accountable-health-communities-ahc-model-fact-sheet.
[3] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 3, The Root Causes of Health Inequity. Available at: https://www.ncbi.nlm.nih.gov/books/NBK425845/.
[4] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. December 2023. Available at: https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.

## A. Measure Overview

The Screening for SDOH measure assesses the total number of patients 18 years or older screened for "health-related social needs", or HRSNs, during their ASC care. The five HRSNs specified by the measure are food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety as described in Table 1 below.

**Table 1. The Five HRSNs for the Screening for SDOH Measure**

| HRSN | Abbreviated CMS Description |
|---|---|
| Food Insecurity | Food insecurity is limited or uncertain access to adequate quality and quantity of food at the household level. |
| Housing Instability | Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence. |
| Transportation Needs | Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. |
| Utility Difficulties | Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. |
| Interpersonal Safety | Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse. |

CMS indicates the development of this measure was informed by the Accountable Health Communities (AHC) Model. This project evaluated whether systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services would impact health outcomes and reduce healthcare utilization and costs. The following summary of the AHC Model provides a context for the interpretation of the results of the project, describing the extent of resources and effort involved.[5]

The AHC Model required participating organizations to perform universal HRSN screening of all community-dwelling Medicare and Medicaid beneficiaries seeking care from the following locations: 1) hospital emergency departments (EDs), labor and delivery units, and inpatient psychiatric units (if applicable); 2) a primary care practitioner or provider; and 3) a practitioner or provider of behavioral health services. Screening was performed using the AHC Model HRSN Screening Tool, which includes a total of 10 questions covering the five areas presented in Table 1 above.

If one or more HRSNs was identified during screening, participating organizations were required to give the beneficiary a "tailored community referral summary" of community service providers that might be able to address each of the HRSNs identified. The summary had to include contact

[5] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation. Affordable Care Act (ACA) Funding Opportunity: Accountable Health Communities (AHC). Funding Opportunity Number: CMS-1P1-17-001 CFDA: 93.650. January 5, 2016.

information (i.e., telephone numbers, addresses, website, and email) and hours of operation for each community service provider that might have been able to address the identified HRSNs. Participating organizations were also required to review the tailored community referral summary with the beneficiary to ensure they understood what resources were available.

High-risk beneficiaries (those with one or more HRSNs and a self-identified history of two or more ED visits in the preceding 12 months) were assigned to either Community Service Navigation ("Navigation") or a smaller control group. Those high-risk beneficiaries assigned to Navigation received in-depth assessment, planning, referral to community services, and follow-up until needs were resolved or determined to be unresolvable over a 12-month period. The control group of high-risk beneficiaries received the tailored community referral summary only.

The Model offered payment of up to $2.57 million to each organization participating in Navigation over the five years of the project. These payments funded infrastructure and staffing needs but did not pay directly or indirectly for any community services.

Despite the extensive support provided for high-risk beneficiaries, Navigation did not yield the hoped-for results. According to the Model Evaluation Report, "findings to date indicate the AHC Model did not markedly increase beneficiaries' connections to community services or HRSN resolution, suggesting that navigation alone may not be sufficient to address HRSNs."[6] Challenges to using community services included ineligibility for services, long waitlists, lack of community resources to resolve needs, and lack of transportation.

Reduced ED visits for high-risk Medicaid (by 3 percent from May 2018 through December 2020) and FFS Medicare (by 8 percent from May 2018 through December 2021) beneficiaries were reported with Navigation.[7] However, it is not clear to us whether the analysis of ED visit rates accounted for the potential confounding effects of the COVID-19 pandemic, which could have impacted the results. A recent, unrelated study showed an initial steep reduction in ED visits during 2020 compared to 2019 levels. Visits rebounded in 2021, but never reached pre-pandemic levels. Overall, ED visit volumes declined by 18% in 2020 and by 10% in 2021. The first quarter of 2022 was 12% below 2019 levels.[8]

The AHC Model Navigation interventions focused on high-risk Medicare FFS and Medicaid beneficiaries; the control group was also composed of high-risk beneficiaries. Therefore, it is unclear whether referrals for lower risk beneficiaries (those with less than two ED visits in the prior year) with HRSNs would have shown benefits. It is also unclear what impact routine screening on other non-Medicare, non-Medicaid populations would have, if any. Consequently, the available evidence does not demonstrate that universal HRSN screening in adults would

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[6] Centers for Medicare & Medicaid Services. (2023). Accountable Health Communities (AHC) Model Evaluation: Second Evaluation Report. CMS Innovation Center. Available at: https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt.
[7] Ibid.
[8] Melnick G, O'Leary JF, Zaniello BA, Abrishamian L. COVID-19 driven decline in emergency visits: Has it continued, is it permanent, and what does it mean for emergency physicians? Am J Emerg Med. 2022 Nov;61:64-67. doi: 10.1016/j.ajem.2022.08.031. Epub 2022 Aug 18. PMID: 36057210; PMCID: PMC9387065.

meaningfully impact the resolution of HRSNs, improve health outcomes, or impact health equity.

### B. Measure Specifications

As noted above, the Screening for SDOH measure assesses the total number of patients 18 years or older who were screened for all five designated HRSNs during their ASC care. It is not clear why these specific HRSNs were chosen. CMS states, "the five domains… were chosen based upon literature review and expert consensus", but the decision-making process that led to the selection of these particular HRSNs over others - such as financial strain, employment, or being able to pay for prescription medications - is uncertain.

**Table 2. Measure Specifications of the Proposed Screening for SDOH Measure**

| Data Element | Specification |
|---|---|
| Numerator | The numerator consists of the number of patients admitted to an Ambulatory Surgical Center (ASC) who are 18 years or older on the date of admission and are screened for all of the following five Health Related Social Needs (HRSNs): Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety during their ambulatory surgical care. |
| Denominator | The denominator consists of the number of patients who are admitted to an ASC and who are 18 years or older on the date of admission. |
| Denominator Exclusions | The following patients can be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf during their ambulatory surgical care. |
| Measure Score Calculation | The Screening for Social Drivers of Health measure will be calculated as the number of patients admitted to an ASC who are 18 years or older on the date of admission screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the date of admission to an ASC. |

"Opt-out" is not defined in the measure specifications but is delineated in supplemental Hospital Inpatient Quality Reporting (IQR) Program guidance. This guidance states, "opt-out could mean refused or that the patient declined to answer. If the patient or authorized representative declines to answer one or more questions related to an HRSN, the patient can be excluded from the denominator of the Screening for Social Drivers of Health measure."[9] Therefore, when patients

[9] Hospital Quality Reporting Program. Frequently Asked Questions: Social Drivers of Health (SDOH) Measures. April 2024. Available at: https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.

are presented with screening questions in all five HRSNs, but choose not to respond to one or more questions, they are removed from the denominator.

### C. Measure Rationale

We agree it is important to understand non-medical needs that may pose barriers to good patient outcomes following ASC services. Increasing awareness of these needs through screening may help centers better appreciate patient circumstances that might otherwise be unapparent. At the same time, we have concerns about certain aspects of the Screening for SDOH measure and related proposals that we discuss below.

### D. Concerns Regarding Screening for Interpersonal Safety

The measure specifications require screening for interpersonal safety. Screening for these issues should only be performed in a safe environment to ensure the risk of violence to the patient is not increased. Best practices dictate screening for interpersonal safety should not be done if another adult is present.[10,11] This assures that positive responses to patient self-administered screenings cannot be observed by others. When screening is staff-administered, this assures conversations cannot be overheard. Without proper conditions, screening may be ineffective or result in patient harm. Several setting-specific distinctions are relevant to the proposed screening in ASCs and other outpatient surgery settings.

First, virtually all ASC patients receive some form of anesthetic, sedation and/or pain medication as part of their care. As a result, patients are required to have a companion to return them home on discharge. While this companion may be anyone, it is often a domestic partner of the patient. This companion typically sits with the patient in the intake area. CMS expects most ASCs would conduct the screening at this point. However, patient self-administered screening at this point would not be private and is unlikely to be effective if the patient is a victim and the companion is a perpetrator.

Following intake, and depending on the protocols each ASC sets, the patient's companion may accompany the patient to the preoperative area, continuing to keep the patient company up until the patient is taken to the procedure or operating room. The companion would later rejoin the patient in the recovery area. This is a patient-centered practice - also seen in hospital outpatient surgical departments - intended to provide support for patients, who value the presence of a family member or friend in these situations. It also helps the companion learn how to assist the patient during further recovery at home.

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[10] The Family Violence Prevention Fund. National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings. 2004. Available at: http://www.futureswithoutviolence.org/userfiles/file/Consensus.pdf.

[11] US Department of Veterans Affairs. Universal Screening of Intimate Partner Violence and Relationship Health with Veterans Experiencing Homelessness. Available at: https://www.va.gov/HOMELESS/docs/White-Paper-VISN-9-Universal-Screening-of-Intimate-Partner-Violence-and-Relationship-Health-FINAL-508.pdf.

Because preoperative and postoperative areas are often semi-private, the design of patient care areas in some ASCs may not provide suitable conditions for screening. Semi-private patient care areas are not unique to ASCs – it is common for preoperative and postoperative patient care areas in hospitals to be semi-private as well. The spaces may have one, two or three walls, with the remainder of the area around the bed surrounded by curtains or the like. Therefore, conversations - such as acknowledging a positive screen and asking if the patient would like a referral for assistance - may not be private even if a companion is asked to step out.

CMS expects that a positive screen for interpersonal safety would result in a referral. However, providing a referral in the context of outpatient surgical care may not be safe. Even in instances when a perpetrator did not accompany the patient to the ASC visit or could be separated from the patient for screening in the preoperative area, discovery is still possible and actually made more likely due to factors related to having had surgery. In addition to recovering from receiving anesthesia, sedation, and/or pain medication for the procedure itself, the patient's continued recovery at home often involves the temporary use of pain medications and need for additional rest or sleep. This can impact a patient's ability to remain vigilant and take necessary steps to avoid detection of having sought help. If resource and/or referral materials were to be provided at discharge and subsequently discovered, additional abuse could be triggered. Perpetrators may also monitor their victim's activities – including phone communication and internet use - so providing referral materials electronically may not offer sufficient protection.

Unfortunately, harm resulting from screening is unlikely to be apparent to ASCs: Federal regulations do not allow ASCs to perform follow-up visits with patients.

CMS should also consider the impact of State-level mandatory reporting requirements for elder abuse, domestic violence, and child maltreatment (in Alabama, Mississippi and Nebraska the age of majority is over 18 and it is unclear to us what would be required in these States). Even if no referral materials were provided at the request of the patient, all States have laws which require healthcare professionals to report suspected elder abuse and child maltreatment. Although State laws vary, healthcare professionals may also be required to report suspected domestic or interpersonal violence. Most States require healthcare professionals to report within 24 hours.

These limits of confidentiality must be disclosed prior to asking questions about interpersonal safety. This helps ensure patients are aware that if they disclose being harmed, reporting to the relevant authorities will be required if the harm is elder abuse or child maltreatment, and may be required depending on State law for other forms of interpersonal abuse. When screening for interpersonal safety is administered by trained staff members, we can feel assured the patient will be made aware of these limits to confidentiality. However, when questions regarding interpersonal safety are patient self-administered, awareness of confidentiality limits cannot be assumed even if this information is included on the questionnaire. This is because patients may not read the instructions.[12,13] In these situations, unintended discovery can result. Consider that

[12] Vésteinsdóttir V, Joinson A, Reips UD, Danielsdottir HB, Thorarinsdottir EA, Thorsdottir F. Questions on honest responding. Behav Res Methods. 2019 Apr;51(2):811-825. doi: 10.3758/s13428-018-1121-9. PMID: 30565012.
[13] Brosnan K, Babakhani N, Dolnicar S. "I know what you're going to ask me" Why respondents don't read survey questions. International Journal of Market Research. 2019 Jan;61(4). doi:10.1177/1470785318821025.

when this occurs, the patient would not have long - recall most States require healthcare professionals to report within 24 hours - to develop a personal safety plan for themselves (and any affected children) and would need to do so while simultaneously recovering from surgery.

The AHC Model Screening Tool, although put forth in these proposals as a tool ASCs could consider, does not include any language about the limits of confidentiality preceding the questions screening for interpersonal safety, which is concerning.

CMS has the option to revise the ASC Screening for SDOH measure to forgo the inclusion of screening for interpersonal safety. CMS did not include screening for interpersonal safety in recent changes to other quality reporting programs when implementing HRSN screening requirements. For example, the requirements for standardized patient assessment data collection for the Inpatient Rehabilitation Facility Quality Reporting Program were amended to include living situation (housing), food, utilities and an updated transportation assessment. However, no requirement for data collection regarding interpersonal safety was adopted. Similarly, revised HRSN requirements for standardized patient assessment data collection were also recently adopted for the Skilled Nursing Facility Quality Reporting Program. These did not include assessment for interpersonal safety either.

If CMS decides to adopt the Screening for SDOH measure for the ASCQR Program, we urge the agency to forgo the inclusion of screening for interpersonal safety. Screening patients during outpatient surgical care presents potential risks to patient safety not seen in other settings such as primary care clinics or inpatient hospital units.

### E. Measure Not Tested in the ASC Setting

In this proposed rule CMS states, "pilot studies screening for HRSNs have been conducted in the HOPD and ASC settings, with clinicians and staff agreeing that HRSN data are important and relevant to collect in these settings to improve patient care and communication as well as to connect patients with social-related services." CMS cited two articles to support this claim.

The first article reported on a pilot of an SDOH screening questionnaire and associated workflow conducted in a single adult ambulatory clinic. Patients who presented for a Medicare wellness, adult annual, or a new patient visit in the Internal Medicine or Family Medicine departments of the clinic were evaluated.[14] As CMS knows, an adult ambulatory clinic providing Internal Medicine and Family Medicine services is not the same as an ASC, so this study does not describe a pilot in an ASC.

The second citation reports on the results of a survey of health professionals from a large integrated health system. The participants were physicians (in the fields of internal medicine,

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[14] Berkowitz RL, Bui L, Shen Z, Pressman A, Moreno M, Brown S, Nilon A, Miller-Rosales C, Azar KMJ. Evaluation of a social determinants of health screening questionnaire and workflow pilot within an adult ambulatory clinic. BMC Fam Pract. 2021 Dec 24;22(1):256. doi: 10.1186/s12875-021-01598-3. PMID: 34952582; PMCID: PMC8708511.

pediatrics, family medicine, emergency medicine, and psychiatry), nurses, case managers, social workers and pharmacists.[15] However, a survey of non-surgical staff does not represent the views of ASCs and their staff.

The assertion that these studies represent a pilot study in an ASC setting, or that the survey responses represent those of ASC clinicians and staff, is not supported by the evidence presented.

CMS has allowed its contractor exemption from processes put in place to assure measures have been properly tested and vetted. If any entity other than a CMS contractor were to develop a measure without testing in the affected setting and without any input from affected parties, objections regarding its suitability for adoption into the associated CMS quality reporting program would be raised, and justifiably so. CMS should not use voluntary reporting periods as a substitute for testing in ASCs.

## F. Measure Evaluation

As a measure developer, we are well acquainted with the standards that measures are expected to meet, especially when being considered for widespread use. We ask that CMS seek to satisfy these standards for all future measure development activities. Meeting established criteria helps give those who are asked to use the measure confidence in its merit as an indicator of performance and its ability to provide valid, reliable and useful data for improvement efforts.

An evaluation of the Screening for SDOH measure was performed as part of the Pre-Rulemaking Measure Review (PRMR) process for the ASCQR Program. CMS's measure development contractor submitted its materials "as is", providing what appeared to be a copy of what had been submitted for the Hospital IQR Program populated with data from the AHC Model. Due to a lack of supporting evidence in the ASC setting, the measure did not meet criteria in multiple areas.[16] Some of the most important deficiencies are presented below.

- No evidence was presented demonstrating that implementing this measure in ASCs would lead to improvement in HRSNs or achievement of health equity. Absent this, the measure does not meet criteria for importance to measure and report.
- No empirical validity testing was performed, so evaluation of the results could not be completed.
- Performance scores were not reported. Therefore, it could not be determined if improving performance on the measure would have a significant impact on quality outcomes.
- The measure developer did not articulate how ASCs could improve performance on the measure.

[15] Schickedanz A, Hamity C, Rogers A, Sharp AL, Jackson A. Clinician Experiences and Attitudes Regarding Screening for Social Determinants of Health in a Large Integrated Health System. Med Care. 2019 Jun;57 Suppl 6 Suppl 2(Suppl 6 2):S197-S201. doi: 10.1097/MLR.0000000000001051. PMID: 31095061; PMCID: PMC6721844.
[16] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. December 2023. Available at: https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.

- No evidence was provided for ASC level reliability so it was not possible to determine whether the measure would meet the minimum threshold.
- The measure developer did not provide evidence of feasibility. Surprisingly, the developer claimed that "many facilities already have an SDOH screening tool integrated into their EHRs." This statement was likely made in reference to hospitals and then not updated for the ASCQR Program submission. Past environmental scans have shown the use of EHRs in the ASC industry to be very limited compared to other healthcare settings. Most ASCs do not have an EHR and SDOH screening tools are not likely to incorporated into the EHRs of those ASCs that do have one.

Based on this independent evaluation, adoption of the measure for the ASCQR Program would not have a scientifically sound basis. The lack of evidence around use of this measure in the ASC setting is concerning. Without testing, there are many unknowns regarding requirements for implementation. For example, it is not possible to determine the FTE impact of staffing the screening and referral processes.

### G. CMS Proposals Regarding Screening Tools

The CMS Strategic Plan around Health Equity indicates one of the agency's goals is the "collection of social needs data in standardized formats across CMS programs"[17], however, the agency is not proposing use of a standardized HRSN screening tool. If the measure were to be adopted, ASCs would be free to select any screening tool to collect these data as long as it contained questions regarding all five HRNS stipulated in the specifications.

CMS points to the AHC HRSN Screening Tool as an instrument ASCs could consider using for the measure. However, during the development and use of this ten-item tool, CMS got permission from the original authors of the questions to use, copy, modify, publish, and distribute the questions for the AHC Model but this permission was *for their use only*.[18] As a result, if others wish to use the questions in this tool, notification of the author and/or citation of the author is required. This means that if an ASC wanted to use the questions, the ASC would be required to "reach out to the screening question author to notify them of their plan to use it," to "cite the screening item appropriately," or both.[19] As a practical matter, this would require the center to footnote every single question if they chose to use the AHC HRSN Screening Tool. And for certain questions, the ASC would additionally need to contact the question's author to notify the author that the ASC planned to use the question during screenings.

CMS indicates ASCs could consider other tools, such as those compiled in a table presented on the Social Interventions Research and Evaluation Network (SIREN) website. However, the

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[17] Centers for Medicare & Medicaid Services. CMS Strategic Plan: Health Equity Fact Sheet. Available at: https://www.cms.gov/files/document/health-equity-fact-sheet.pdf.
[18] Centers for Medicare & Medicaid Services. (2021). The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf
[19] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Health-Related Social Needs Screening Tool Citation and Notification Information. Available at: https://www.cms.gov/priorities/innovation/media/document/ahcm-screening-tool-citation

SIREN website states, "inclusion of a tool… does not necessarily mean that the tool or the questions contained therein has been 'validated'. While some specific questions or tools have been studied, validity has many different dimensions (e.g., criterion validity [predictive, convergent], construct [structural]), and none of the tools below has been vetted through all steps of gold standard measure development or had all types of validity assessed."[20]

Considering the scope of providers across which CMS intends to adopt this measure, validated screening tools are essential. As CMS is aware through its development of CAHPS surveys, detailed testing assures patient questionnaires are scientifically sound. However, as the measure has been proposed, it would be entirely possible for a facility (of any type, including hospitals) to ask one question regarding each of the five identified HRSNs and meet numerator criteria.[21] Technically, any facility could author their own questions in each of the five domains. Absent a requirement to use validated tools or even a standardized screening instrument, the validity of the measure results is compromised.

A recent FAQ document for the Hospital IQR Program indicates that CMS "anticipates additional emphasis on standardized and validated screening instruments in future versions of these measure [sic]."[22] Giving ASCs (and others) initial flexibility, then subsequently requiring something different could leave providers in the unenviable position of having to start over. If the agency anticipates requiring the use of screening instruments with specific characteristics, CMS should make this clear from the start. CMS should provide a list of screening tools it considers adequately tested to ensure their validity.

### H. Proposal to Allow Use of HRSN Screening Data from Other Care Settings

CMS has proposed, "ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we propose that the… ASC could use that information for purposes of reporting the measure in lieu of screening the patient." The same proposal has been made for HOPDs.

ASC care is scheduled only by referral from a physician on staff at the center. It's possible a patient would have been screened at the physician's office prior to being scheduled, and some ASCs may wish to consider the option to use that screening if it can be obtained. Therefore, we support the proposal to allow use of screenings performed in other settings instead of re-screening at the ASC.

### I. Other Unintended Consequences

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[20] Social Interventions Research & Evaluation Network. Social Needs Screening Tool Comparison Table. Available at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.
[21] Hospital Quality Reporting Program. Frequently Asked Questions: Social Drivers of Health (SDOH) Measures. April 2024. Available at: https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.
[22] Ibid.

CMS intends to require all healthcare facilities to screen for HRSNs. The scope of these requirements will undoubtedly lead to repetitive screening of many individuals as they move through the healthcare system for various needs. We do not see any indication that CMS has evaluated the impact of repeated referrals for the same individual on the capacity of local organizations to respond to the increased volume of referrals while still providing services efficiently. Many community service providers and local/county departments of health and human services operate within the constraints of limited staff and infrastructure. Streamlined referrals promote labor-saving and productive use of those resources, whereas repetitive referrals may prove counterproductive. CMS should conduct a formal evaluation to determine what impact its widespread adoption of screening requirements has on community service providers.

### J. Proposed Data Submission and Reporting Requirements

CMS proposes to allow ASCs to voluntarily submit data for this measure for the CY 2025 reporting period "to provide a transition period for healthcare facilities to select and integrate screening tools into their clinical workflow processes." Mandatory reporting for the measure is proposed to begin with the CY 2026 reporting period/CY 2028 payment determination. Data would be submitted in aggregate on an annual basis through the HQR system.

We do not support this timeframe for implementation. It does not account for the significant amount of time and resources that ASCs will be putting into meeting requirements for mandatory reporting of OAS CAHPS Survey measure, which begins in 2025. Further, if CMS decides to retain the requirement to screen for interpersonal safety in the ASC measure, it does not allow sufficient time for any necessary redesign of patient care areas to create a private location for screening, to redesign workflow to accommodate the need for privacy, to determine State reporting requirements and incorporate those into screening protocols, and to perform the necessary staff training.

If the measure is adopted, the timeline for reporting should be shifted by a minimum of one year such that the Screening for SDOH measure would be voluntary until the CY 2026 reporting period at the earliest and not mandatory until the CY 2027 reporting period/CY 2029 payment determination.

### K. Underestimation of the Information Collection Burden for the Screening for SDOH Measure

CMS used data from the ASC QC's Patient Fall measure benchmarking data to calculate the information collection burden associated with this measure because it applies to all patients rather than just Medicare patients. In doing so, CMS used the total of roughly 10.5 million admissions analyzed. However, that figure reflects admissions for roughly 2200 ASCs and would need to be adjusted to account for the total of approximately 4500 ASCs participating in the ASCQR Program. We are certain this was inadvertent, but the cost estimates should be revised.

### L. Summary

Being aware of HRSNs is important, yet we cannot support adoption of this measure as proposed. We are uncomfortable with the requirement for universal screening for interpersonal safety in the context of outpatient surgical care and cannot support any proposal that may carry risk of patient harm. If the measure is adopted for the ASCQR Program, we ask that this topic not be included per the precedent set for the Inpatient Rehabilitation Facility Quality Reporting Program and the Skilled Nursing Facility Quality Reporting Program.

## III. Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure

Related to its efforts to encourage systematic screening for patient HRSNs, CMS is also proposing to adopt a related measure that would evaluate positive screening rates. This Screen Positive Rate for SDOH measure has also been proposed for the Hospital OQR Program.

### A. Measure Specifications

The Screen Positive Rate for SDOH measure is characterized as a "process measure" that would calculate the rate of patients who screened positive for one or more of five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) in relation to the number of ASC patients who were 18 years or older on the date of admission and who were screened for all five HRSNs. The measure specifications are presented in Table 3 below.

**Table 3. Proposed Screen Positive Rate for SDOH Measure Specifications**

| Data Element | Specification |
|---|---|
| Numerator | The numerator consists of the number of patients receiving care at an ASC who are 18 years or older on the date of admission, who were screened for all five HSRN, and who *screen positive* for having a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety. |
| Denominator | The denominator consists of the number of patients receiving care at an ASC who are 18 years or older on the date of admission and are screened for all of the following five HSRN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) during their care. |
| Denominator Exclusions | The following patients can be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf during their ambulatory surgical care. |
| Measure Score Calculation | The result of this measure would be calculated as five separate rates. Each rate is derived from the number of patients admitted to an ASC and who are 18 years or older on the date of |

| | |
|---|---|
| | admission, screened for an HRSN, and who screen positive for each of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety—divided by the total number of patients 18 years or older on the date of admission screened for all five HRSNs. |

As discussed above, the meaning of "opt-out" as described in supplemental IQR Program guidance indicates that if the patient or authorized representative declines to answer one or more questions related to an HRSN**,** the patient can be excluded from the denominator of the Screening for Social Drivers of Health measure and "this would then also exclude them from the Screen Positive Rate for Social Drivers of Health measure for all HRSNs."[23] Therefore, when a patient presented with screening questions in all five HRSNs chooses not to respond to one or more questions, that patient would be removed from the denominator of both measures.

**B. Measure Calculation**

This measure is not typical, in that it doesn't result in a score reflecting facility performance. CMS proposes ASCs be required to report the Screen Positive Rate for SDOH measure as the rate of patients who screened positive for each of the five core HRSNs domains of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. That is, centers would be required to calculate a separate rate for each of the five HRSNs using the same denominator. ASCs would then be required to report the five individual rates separately at the time of data submission.

**C. Measure Rationale**

When this measure was submitted for review during the PRMR for ASCs, the following description of the measure rationale was provided: "CMS has recognized the importance of making SDOH measures standard across programs, identifying the development and implementation of 'measures that reflect social and economic drivers' as a key priority and measurement gap to be addressed through Meaningful Measures 2.0."

CMS believes requiring ASCs to report the rates of patients who screened positive for each of the five core HRSNs would allow ASCs to capture the magnitude of these needs.

**D. Measure Evaluation**

The measure is characterized as a process measure, meaning a measure that, per CMS, "focuses on steps that should be followed to provide good care. There should be a scientific basis for believing that the process, when executed well, will increase the probability of achieving a

[23] Hospital Quality Reporting Program. Frequently Asked Questions: Social Drivers of Health (SDOH) Measures. April 2024. Available at: https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.

desired outcome."[24] No evidence was provided to demonstrate that the process of calculating the screen positive rate for the various HRSNs leads to better or more equitable outcomes.

An evaluation of the Screen Positive Rate for SDOH measure performed for the PRMR process for the ASCQR Program identified many unmet criteria.[25] The nature of the measure itself and the absence of testing in the ASC setting led to deficiencies in supporting data, including:

- No empirical validity testing for ASCs was reported.
- No ASC reliability data was reported, so it could not be determined whether the measure would meet the minimum reliability threshold.
- Because this measure does not reflect quality/equity of care, no performance scores or indication of a performance gap was provided to support the importance of using the measure, and there was no articulation of how ASCs could improve performance.
- No evidence of feasibility was presented, though the developer again claimed that "many facilities already have an SDOH screening tool integrated into their EHRs." As noted above, we believe this statement was copied from the submission for the Hospital IQR Program review and was not updated for the ASC review process because the measure was submitted "as is".

The extent of unmet measure criteria is very concerning. Testing in the ASC setting is an important part of developing sound measures. We do not condone CMS's ongoing practice of omitting keys steps in the measure development process.

### E. Measure Rates Do Not Help Providers or Consumers

While CMS states the measure results provide actionable data and suggests the data could be used to capture the magnitude of need, to track the prevalence of specific HRSNs among patients over time, and to stratify risk, there are several reasons the calculated rates may not actually be helpful to ASCs (or others using the measure).

First, the data used to calculate the measure would be derived from responses to whatever screening questionnaire was used, and as seen above, there is no requirement that the screening tool itself or any of the questions asked be validated.

Second, the five rates would be skewed because of the exclusion of patients who did not respond to all the questions posed. If, for example, the patient responded affirmatively to items about food insecurity, housing instability, transportation problems, and utility difficulties, but elected not to respond to questions about interpersonal safety, per the measure FAQs, that patient would be dropped from the denominator. As a result, their positive responses for four of the items

[24]Centers for Medicare & Medicaid Services. Measures Management System. Measure Type Definitions. Available at: https://mmshub.cms.gov/about-quality/new-to-measures/types.
[25] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. December 2023. Available at: https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.

would not be included in the numerator. The final rate reported for each of the five categories would not reflect all the positive responses received.

Third, the calculated rates would be heavily dependent on the extent to which patients participated in screening. Participation is, of course, completely voluntary and patients may opt out of screening entirely or decide not to answer certain questions. Further, even if patients elect to participate and decide to complete the entire screening, they may decide not to disclose all or some of their unmet needs despite having them. Consequently, there is no reason to believe the rates derived from the measure data reflect the actual rate of unmet needs. As a result, the calculated rates have limited utility for ASCs (and all other healthcare facilities) and are not suitable for the purposes CMS has suggested.

CMS indicates, "[t]his measure is not intended for comparison of screen positive rates of HRSNs between healthcare facilities." We agree. ASCs should not use the information to compare or benchmark performance since meaningful comparisons are not possible.

There is also the matter of the measure results not being useful to consumers. Although the measure data are not a reflection of the quality and equity of care provided at ASCs, the rates would be publicly reported. We and many others think it would be a source of confusion for consumers. The data would be presented in the setting of other quality data, so it would be natural for a consumer to be inclined to interpret the scores in that context. Anyone who is not well-versed in the measure cannot be expected to immediately understand that these rates cannot be used in the usual manner (such as "a higher rate is better", or "a lower rate is better") despite the information having been presented as quality data. We hope CMS will reconsider the matter of publicly reporting data for this measure. It has no tie to quality or equity of care and is likely to be unclear to the public.

### F. A More Impactful Way to Advance Health Equity Exists

When the resources of the entire health system are to be engaged, CMS should ensure they are thoughtfully deployed and focused on actions proven to produce results. Instead of adopting this measure, CMS should redirect its efforts toward measuring disparities in outcomes. We know the agency can do this because it has analyzed selected ASC claims-based measures for evidence of disparities. Three of the measures included in the ASCQR Program (Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs, Hospital Visits After Orthopedic ASC Procedures, and Hospital Visits After Urology ASC Procedures) have undergone these analyses.[26]

During the evaluation of these measures, two methods were used for disparities testing. First, patient-level analysis was performed using claims data to determine whether risk adjustment for Medicaid dual-eligibility status, African American race, or the AHRQ-validated SES index

[26] Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (CORE). Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers: Measure Technical Report, Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures: Measure Technical Report, and Hospital Visits after Urology Ambulatory Surgical Center Procedures: Measure Technical Report. 2017.

affected measure scores. The facility-specific measure scores with and without adjustment for each of these variables were compared. While disparities in ASC outcomes were not detected at the time of testing, this method could be readily applied to more recent claims not only for ASCs but also for other surgical providers.

The second type of disparities testing was performed at the facility level. This analysis assessed whether ASCs with a high proportion of dual-eligible patients, African American patients, or low-SES patients (as identified by the AHRQ SES index) performed as well on the measure as ASCs with lower proportions of these patients. This analysis was performed by categorizing ASCs into quartiles based on proportions of Medicaid dual-eligible, African American, and low-SES patients. The distribution of measure scores across the lowest and highest quartiles was then examined. Although ASC outcomes were not impacted by these SES variables, this method could be used to identify facilities with disparities in outcomes.

CMS would certainly not be limited to these particular analyses to perform disparities testing. Other analyses using alternative parameters could be used to evaluate claims across surgical settings. With information like this, all surgical facilities could have access to actionable data to drive efforts to reduce identified disparities. This is an opportunity to achieve near-term advances in equitable outcomes and would move the agency toward realizing it strategic goals more quickly than the proposed Screen Positive Rate for SDOH measure.

### G. Proposed Data Submission and Reporting Requirements

CMS has proposed ASCs be required to submit aggregate data representing the total number of positive results for each of the five screening areas separately in addition to the denominator of the total number of patients screened for all five of the HRSNs who meet criteria for inclusion. Data would be submitted on an annual basis through the HQR system.

As with the Screening for SDOH measure, CMS proposes to allow ASCs to voluntarily submit data for the Screen Positive Rate for SDOH measure for the CY 2025 reporting period. Mandatory reporting would begin with the CY 2026 reporting period/CY 2028 payment determination.

We do not support this timeframe for implementation for the same reason we do not support the timeframe for the Screening for SDOH measure: it does not account for mandatory reporting of the OAS CAHPS Survey measure, which begins in 2025, and does not allow sufficient time for the amount of work that would need to be done for the Screening for SDOH measure, if it were to include interpersonal safety. If the measure is adopted, the timeline for reporting should be shifted by one year such that the Screen Positive Rate for SDOH measure would be voluntary for the CY 2026 reporting period and mandatory beginning with the CY 2027 reporting period/CY 2029 payment determination.

### H. Lack of Consensus Among Affected Parties

CMS has not met the statutory requirement that the measure reflect consensus among affected parties. The traditional method for establishing consensus is endorsement by a consensus-based entity. However, this measure has never been endorsed for use in ASCs, nor has it been endorsed for use in any other setting for which the measure has been either adopted or proposed. CMS believes bypassing endorsement is justified based on the urgency of the matter and its desire to implement the measure as soon as possible.

Alternative methods of achieving consensus among affected parties have not been demonstrated. The Hospital Pre-Rulemaking Measure Review Recommendation Group was not able to reach consensus around the measure. The measure cannot be said to meet the requirement for consensus through broad acceptance of the measure by ASCs or through use of the measure by ASCs. ASCs were not involved in the development of the Screen Positive Rate for SDOH measure, so the development process did not provide an opportunity to establish consensus. ASC stakeholders have not supported the measure in public comments.

CMS has not met its obligation to ensure consensus among the parties affected by the adoption of the Screen Positive Rate for SDOH measure in the ASC setting. Therefore, the measure should be withdrawn from consideration for the ASCQR Program.

### I. Summary

We do not support the adoption of the Screen Positive Rate for SDOH for the ASCQR Program. The absence of consensus among affected parties is apparent. In addition, the lack of evidence supporting a connection to improvement in quality and equity of care makes it unsuitable for application in any quality reporting program. As a measure developer, we recognize that asking health care professionals to measure a process that we hope will be helpful but cannot demonstrate will make a meaningful difference diverts resources from other, evidence-based practices shown to have a measurable impact.

Rather than promoting and adopting process measures that do not have a clear connection to improving outcomes and equity, CMS should contract for claims-based measures that evaluate surgical care outcomes stratified by patient characteristics such as race and ethnicity, SES, dual eligibility and other related factors. Outcome measures such as these could identify performance gaps and drive improvement initiatives. We encourage CMS to set aside the Screen Positive Rate for SDOH measure and apply its measure development resources toward evaluating disparities in surgical outcomes.

## IV. Proposed Adoption of the Facility Commitment to Health Equity (FCHE) Measure

The Facility Commitment to Health Equity (FCHE) measure is a structural measure intended to assess commitment to health equity by evaluating ASC activities in several domains: strategic planning, data collection, data analysis, quality improvement, and leadership engagement. CMS has indicated, “this measure is specifically important to include in the ASCQR program to ensure leadership of ASCs are committed to equity-focused organizational competencies that enhance awareness, understanding, and implementation of improvements to address inequities in surgical care experience and recovery that may be faced by individuals of different groups and

circumstances. By doing so, this creates an institutional culture of equity that promotes optimal health for all patients served in these settings."[27]

### A. Measure Specifications

As proposed, ASCs would have to attest to performing a variety of activities within the five domains of strategic planning, data collection, data analysis, quality improvement and leadership engagement as displayed in Table 4 below.

**Table 4. Facility Commitment to Health Equity Measure: the Five Attestation Domains and Required Elements for Each Domain**

| **Domain 1: Equity is a Strategic Priority** | **Required Elements** |
|---|---|
| Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements. | (A) Our facility strategic plan identifies priority populations who currently experience health disparities.<br>(B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals.<br>(C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals.<br>(D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations. |
| **Domain 2: Data Collection** | **Required Elements** |
| Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities. | (A) Our facility collects demographic information (such as self-reported race, national origin primary language and ethnicity data), and/or social determinant of health information on the majority of our patients.<br>(B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information.<br>(C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using an EHR technology. |
| **Domain 3: Data Analysis** | **Required Element** |
| Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities. | (A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards. |
| **Domain 4: Quality Improvement** | **Required Element** |
| Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients. | (A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities. |

[27] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. December 2023. Available at: https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.

| Domain 5: Leadership Engagement | Required Elements |
|---|---|
| Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities. | (A) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity.<br>(B) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors. |

According to the agency, "these domains were developed based on the recommendations from a technical expert panel (TEP) that informed our initial selection and development of this measure." The nine-member TEP did not include any ASC representatives. A completed draft of the measure was given to the TEP and discussed in a single two-hour virtual meeting. No additional meetings of the TEP were held in follow-up. The TEP only considered the hospital version of the measure; no other settings were discussed.[28]

### B. Measure Calculation

As proposed, each of the domains described above would be worth a point, with a total of five points possible. The maximum score on the measure would be 5 out of 5. An ASC must perform every element within the domain to receive a point for that domain. CMS has not proposed to offer any partial credit for meeting some, but not all, of the required elements when a domain has more than one.

### C. Measure Rationale

In proposing this measure CMS states, "strong and committed leadership from healthcare facility management is essential in shifting organizational culture to reduce health disparities and reach health equity goals." The citation supporting this assertion is for a study regarding the use of guiding coalitions to spread best practices for acute myocardial infarction care. The study never mentions health disparities or reaching health equity goals - the words "disparity" and "equity" do not appear in the publication.[29] The agency then points to publications by The Joint Commission and the Agency for Healthcare Research and Quality which do not discuss health equity or disparities. Finally, the agency references research by the Institute for Healthcare Improvement, but the citation is for an opinion piece, not for peer-reviewed scientific research.

Since these publications do not establish an evidential basis for this measure, we turned to the rationale provided when the measure was submitted for the PRMR process for additional insight. This rationale states, "numerous studies have shown that among Medicare beneficiaries, racial

[28] Centers for Medicare & Medicaid Services. Summary of Technical Expert Panel (TEP) Meeting # 1 November 16, 2021: Health Equity Quality Measurement Hospital Commitment to Health Equity Measure. Available at: https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf.
[29] Bradley EH, Brewster AL, McNatt Z, Linnander EL, Cherlin E, Fosburgh H, Ting HH, Curry LA.(2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Quality & Safety, 27(3), 218-225. https://pubmed.ncbi.nlm.nih.gov/29101290/.

and ethnic minority individuals often receive lower quality of hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications. Readmission rates for the most common conditions in the Hospital Readmissions Reduction Program are higher for black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction. To ensure that all patients receive excellent care when hospitalized regardless of their individual characteristics, strong and committed leadership from hospital executives and board members is essential."[30]

Evidence of gaps in equity of hospital care is just that – hospital evidence. A clear rationale for implementing the measure based on evidence of ASC equity gaps has not been articulated. As noted above, CMS analyses performed on certain ASCQR Program claims-based measures to determine whether ASC outcomes varied by demographic characteristics including race and socioeconomic status did not show any disparities. Without any evidence of disparities in ASC care outcomes, it is not reasonable to impose these extensive requirements.

**D. Measure Evaluation**

A general evaluation of the measure specifications against well-established standards was conducted as part of the PRMR process.[31] The findings of concern are summarized below:

- CMS did not provide an empirical test of measure validity.
- It could not be determined if assessing ASC commitment to health equity in this manner would allow centers to improve.
- CMS did not submit performance scores to support the importance of using the measure in ASCs. Whether improvement would have a significant impact on outcomes could not be determined.
- Some of the domain criteria were considered vaguely defined.
- No ASCs were consulted regarding the usability and value of the measure.
- The feasibility of the measure was questioned. It could not be determined that ASCs have access to the people, processes and technology needed for data collection and reporting. The burden associated with making the needed investments was noted.

This evaluation identified concerns associated with the measure properties but did not assess feasibility at the domain level. CMS says it recognizes, "ASCs have governance structures and operational circumstances that are distinct from hospitals", but this is not reflected in the measure specifications. Because the domains and required elements were not modified from the original hospital measure (other than to change "certified electronic health record technology" to "electronic health record technology"), it is clear CMS has assumed ASCs have the same

[30] Partnership for Quality Measurement. Pre-Rulemaking Measure Review. Facility Commitment to Health Equity: Ambulatory Surgical Center Quality Reporting Program. Measure Submission Export. Retrieved December 19, 2023.
[31] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. December 2023. Available at: https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.

operational infrastructure, the same scope of administrative and support personnel, the same data collection and analysis capabilities, and the same technological tools as hospitals.

As a result, we remind CMS of some of the salient differences between hospitals and ASCs. CMS has estimated that approximately 73 percent of ASCs would be classified as small businesses according to the Small Business Administration size standards [72 Fed. Reg. 66901]. The predominance of small facilities is corroborated by CMS data indicating a median of two operating/procedure rooms per facility (mean = 2.5). Not only do ASCs tend to be small, but they also employ a much smaller number of individuals than hospitals. The ASC Association's ASC Salary & Benefits Surveys conducted over multiple years have shown that the median number of total full-time employees is 21 to 22, including both clinical and non-clinical staff.[32] Small volume ASCs (those performing less than 1999 cases per year) employ less than seven FTEs.[33] Of the facility types that provide surgical services, ASCs receive the lowest reimbursement for the services they perform. As a result, ASCs must be "lean". In addition to providing patient care, clinical staff typically serve in multiple additional roles to comply with all the Federal, State, and other applicable requirements for licensure, certification and quality reporting.

One of the most unfounded assumptions of this measure is that all ASCs have EHRs, yet most do not. This is primarily the result of ASCs having been excluded from the provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. The HITECH Act authorized financial incentives for hospitals and clinicians to adopt and meaningfully use certified electronic health record technology, or CEHRT. CMS implemented these financial incentives through the Promoting Interoperability Program to encourage health care facilities and professionals to adopt and meaningfully use CEHRT. Because ASCs were not included in the provisions of the Act, they were subsequently ineligible for financial incentives under the Promoting Interoperability Program. Although ASCs were eligible to apply for a very limited portion of $2 billion in grant and loan money available to states for investment in health information technology, this eligibility did not result in a significant increase in the use of EHRs in the ASC industry. The high cost of EHR implementation and maintenance continues to be a barrier to EHR use in ASCs.

CMS cites an article describing an informal EHR utilization survey conducted by the Ambulatory Surgical Center Association, which indicated that 54.6 percent of the respondents used an EHR in their ASC.[34] While this may reflect the use of EHRs in the pool of survey respondents, this figure does not accurately reflect the use of EHRs in the ASC industry as a whole. It is also worth considering that individuals within the ASC industry define an EHR in varying ways; for example, some would consider an endoscopic report writer to be an EHR

[32] Tucker K. (December 2023). ASCA Survey Shows Salaries and Caseloads Rising. ASC Focus. Available at: https://www.ascfocus.org/ascfocus/content/articles-content/articles/2023/digital-debut/asca-survey-shows-salaries-and-caseloads-rising.
[33] Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgery Center Environmental Scan. July 2008. Contract No. GS-10F-0096T.
[34] Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs.

while others would not. The author noted it was "hard to draw any definitive conclusion from a small sample," referencing the total of 260 respondents. The same article points to vendor estimates that put EHR adoption at around 20 percent of ASCs. We find this a more credible estimate: vendors sell and maintain these systems and are more likely to understand the market penetration of their products.

The FCHE measure would require ASCs to stratify key performance indicators by demographic and/or social determinants of health variables to identify equity gaps. This assumes ASCs generally have the personnel and technology available to develop patient-level data for all the quality metrics they track, to stratify each metric by demographic and/or SDOH variables, and to analyze that data to identify equity gaps. We cannot emphasize how challenging this would be for the average ASC. Performing such analyses and determining if the results indicate a statistically significant difference in performance based on demographics and/or SDOH is not a skill set likely to be found among ASC staff.

The requirements further assume ASCs have the personnel and technological tools to allow them to produce a performance dashboard, but not all ASCs can do this. While all Medicare certified ASCs maintain an ongoing, data-driven quality assessment and performance improvement program, there is no requirement that the data produced by the program be incorporated into a performance dashboard.

Although large organizations such as hospitals typically perform strategic planning, it is not a common practice among small businesses, including ASCs. While ASCs could develop a strategic plan, most do not have the technological tools and data analysis skills needed to "identify priority populations who experience health disparities" within the communities they serve and determine how those populations within the community intersect with the patients referred to the center.

ASCs do not employ case managers, social workers or other related professionals. This reflects Federal regulations that restrict ASC care to surgical services only; these services are further limited to the immediate preoperative, intraoperative and postoperative period. ASCs may not perform preoperative or postoperative clinic visits. These Federally imposed constraints are reflected in ASC staff expertise, which is highly focused on excellence in preoperative, intraoperative and postoperative patient care. ASCs do not have in-house access to subject matter experts in culturally sensitive collection of demographic and/or social determinant of health information.

Hospitals have greater staff resources and can readily assign team members to participate in local, regional, or national quality improvement activities focused on reducing health disparities on behalf of their organization. With limited staff, ASCs would have to consider how personnel resources could be redirected from current priorities such as participation in organizations focused on ensuring best practices in infection control and patient safety.

The language in the measure requirements also includes references to "chief executives" (the plural being a direct quote of the measure specifications) and the "entire facility board of

trustees." This level of administrative and leadership complexity is rarely seen. ASCs are led by a governing body (which may be as small as one individual if the ASC has one owner) that has direct oversight of the ASC's mandatory quality program and other operations. Centers typically have one administrator who leads day-to-day operations, and it is not unusual for this individual to have other roles and responsibilities such as direct patient care, compliance, staff training and so forth.

In short, the requirements of the FCHE measure presume ASCs have what hospitals have: complex operational infrastructure, a broad scope of administrative and support personnel, sophisticated data collection and analysis capabilities, and advanced technological tools. The only change CMS made in adapting this measure to the ASC setting was to revise CEHRT to EHRT. That change is not enough.

In fact, from the ASC perspective, this measure is just as much about facility infrastructure, personnel, data analysis capabilities and technological tools as it is about commitment to equity. Achieving a 5/5 score on this measure would be very challenging for ASCs that have an EHR and impossible for those that do not. Yet this would not necessarily reflect a lack of commitment to equity. The measure must be adapted for small facilities to prevent biased scores that favor large facilities with greater resources.

CMS has proposed to adopt the related Hospital Commitment to Health Equity for the Hospital OQR Program. While we would normally welcome the resultant comparisons, in this case, HOPDs would clearly be in a better position to comply with the measure requirements, which would be the same for both the Hospital IQR and Hospital OQR Programs. Because HOPDs are integrated into their hospitals, any actions required to meet measure requirements for the Hospital IQR Program are already underway. Nothing different would need to be done to meet requirements for the Hospital OQR Program.

### E. Pre-Rulemaking Measure Review (PRMR)

As noted previously, this measure was conceived as a hospital measure. As such it was reviewed during the 2021-2022 Measures Under Consideration process for the Hospital IQR Program. The Hospital Workgroup did not support the measure for rulemaking. A "do not support" recommendation for a measure presented by CMS is rare, and an indication that the workgroup found substantive issues with the measure. Though ultimately the MAP Coordinating Committee (which reviews workgroup recommendations) voted to conditionally support the measure, overriding the Hospital Workgroup, the original recommendation is worth noting. The MAP Coordinating Committee's conditional support was contingent upon measure endorsement to address reliability and validity concerns. Their recommendation noted, "the literature currently does not closely link this measure to clinical outcomes" and "there is insufficient information to evaluate the potential impact of this measure on quality of care."[35] CMS did not submit the measure for endorsement as recommended, and subsequently adopted the measure for the

[35] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https:// www.qualityforum.org/WorkArea/linkit.aspx? LinkIdentifier=id&ItemID=96698*.

Hospital IQR Program in 2022 under the exception clause of 1886(b)(3)(B)(viii)(IX)(bb) of the Social Security Act.

In the time that elapsed following the PRMR for the hospital version of the measure and the presentation of the measure for PRMR for the ASC setting, CMS did not address any of the concerns that had been raised earlier. In fact, the measure was presented "as is" for review.

The PRMR for the ASC FCHE measure took place earlier this year. The Hospital Committee discussion of the commitment to health equity measures was not limited to ASCs, but rather encompassed ASCs, HOPDs, and Rural Emergency Hospitals simultaneously. We attended the meeting remotely and can attest that the concerns we shared in our comments were not included in the slide providing a summary of the comments and were not discussed before decisions were made. Because the only participants allowed to engage in the discussion were CMS, Battelle staff, and members of the Committee, there was no opportunity to raise the issues that were omitted, such as the difficulty posed by the inclusion of electronic health records in the required elements.

When asked about the possibility that facilities might not have the infrastructure in place to meet measure requirements, CMS responded by suggesting that, for those facilities, the measure would be "a catalyst for capacity building efforts." Others suggested it would be important for ASCs to "catch up" to the inpatient setting.[36]

### F. Proposed Data Submission and Reporting Requirements

CMS proposes to require ASCs to submit their yes/no attestation responses using the HQR system each year. No voluntary reporting period has been proposed. As proposed, reporting of the measure would be mandatory beginning with the CY 2025 reporting period for the CY 2027 payment determination.

We cannot support this implementation timeframe. From a practical standpoint, it is hard to understand how ASCs would be able to meet domain requirements when they have not yet begun to collect SDOH/HRSN data: as proposed, data collection for the Screening for SDOH and Screen Positive Rate for SDOH measures would be voluntary in 2025 and not mandatory until 2026. If adopted as proposed, this means the FCHE measure would be mandatory a year prior to the Screening for SDOH and Screen Positive Rate for SDOH measure would be mandatory.

It is completely unreasonable to expect ASCs to implement all requirements for the FCHE measure between the issuance of the final rule in November 2024 and the end of the data collection period in December 2025. Setting aside all the issues related to infrastructure, personnel, processes and technology described above, there would not be sufficient time to establish the foundation of data needed to inform the activities prescribed by the measure. As noted above, the assertion that ASCs already collect data regarding HRSNs (and do so electronically) is unfounded.

[36] Partnership for Quality Measurement. PQM PRMR Hospital Recommendation Group Meeting 1/198/2024 (Day 2 of 2). Available at: https://p4qm.org/media/2751.

CMS must formally assess the current capabilities of the ASC industry through a detailed environmental scan prior to any additional rulemaking action around this measure. The results of the environmental scan should inform the restructuring of the measure so that ASC commitment to health equity can be determined using attainable requirements. An environmental scan would also allow CMS to set a manageable implementation timeframe.

If CMS determines it will not conduct an environmental scan and proceeds to adopt the measure without one, mandatory reporting should be delayed by a minimum of five years from the proposed timeline. Taking all the steps that would be needed to meet the requirements of this measure in its current form – including the selection and implementation of an EHR - would be a massive, multi-year undertaking, requiring a level of effort and expense that would far exceed that required to implement the OAS CAHPS measure in 2025. This delay would also help accommodate those ASCs that will be facing the herculean efforts required to prepare for mandatory reporting of the THA/TKA PRO-PM in the CY 2028 reporting period. CMS could allow voluntary reporting of the FCHE measure in the interim.

### G. Summary

We do not support the adoption of the FCHE measure. Applying requirements "as is" across the continuum of care based on competencies expected of hospitals reflects a one-size-fits-all approach that is unreasonable. Domain-level expectations have not been adapted to account for differences between hospitals and ASCs in infrastructure, personnel, and the availability of data analysis and technology resources. CMS has made, and continues to make, many assumptions regarding what ASCs are reasonably capable of doing with respect to quality measurement. These assumptions manifest themselves in the ongoing proposal (and subsequent adoption) of hospital measures with requirements that are beyond the reach of the typical ASC.

CMS has stated this measure is a "starting point" - a "step" toward achieving health equity. While this may prove to be a "step" for hospitals, it will be a hurdle, if not a cliff to scale, for ASCs that are not wholly owned by hospitals (3% of the industry). We reiterate that no further action on this measure should be taken until an ASC environmental scan has been conducted to inform the measure specifications and implementation timeline.

## V. CMS Request for Information Regarding Development of Frameworks for Specialty Focused Reporting and Minimum Case Number for Required Reporting

The current measure set for the ASCQR Program includes measures that are applicable to all ASCs, as well as specialty-specific measures only applicable to certain ASCs based on their case mix. When an ASC does not perform certain specialty procedures, the center is required to attest to "zero cases" during the process of submitting quality measure data to CMS.

Per the agency, there are occasionally times when an ASC does not complete the zero-case attestation during the data submission process, which results in the center not being eligible for their full payment update, which is subsequently appealed by the ASC. One of the reasons CMS

says it is considering restructuring the ASCQR Program is to reduce burden by removing the zero-case attestation requirement.

CMS has presented two ideas for this restructuring and has requested feedback regarding these potential future approaches. One alternative is termed "Specialty-Select"; the other has been dubbed "Specialty Threshold". At present, the ASCQR Program does not have enough measures in the various specialties to support the changes CMS is contemplating.

In addition, we have no sense of how CMS would balance reporting burden across single-specialty and multispecialty centers using a specialty-specific approach. For consumers to have equally informative quality data for a given specialty, regardless of whether offered in a single-specialty or a multispecialty setting, all facilities performing the service would need to report on any designated panel of specialty measures. Multispecialty centers would have to shoulder a significantly greater reporting burden due to the need to report on specialty-specific measures for each service line. This is not a scenario we support.

We believe both frameworks CMS has presented for feedback would, on balance, introduce additional, unnecessary complexity to the Program and do not support them.

A simpler way to manage the issue of periodic lapses in the completion of the zero-case attestation requirement during data submission would be to implement automated, real-time data validation checks that would identify incomplete fields. Prompts could remind a submitter to address the need for zero-case attestation. Additional alerts could provide user feedback regarding the completeness of data submission.

We appreciate CMS having considered Program modifications to decrease burden. Rather than completely restructuring the program and increasing complexity, we would like to point out other needed Program modifications that could meaningfully reduce burden.

### A. Change the Reporting Requirements for ASC-20: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

The COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure tracks COVID-19 vaccination coverage among HCP in various settings. ASCs are still required to collect data on HCP vaccination rates for at least one week of every month and to submit that data to NHSN on a quarterly basis. The ASC QC and many others – including a nationally recognized association dedicated to infection prevention and epidemiology - have requested annual data submission. Easing data collection and reporting expectations for the measure would help reduce Program burden for all ASCs.

### B. Streamline Data Collection

ASCs have welcomed the change in reporting methodology for ASC-1 through ASC-4. Using the HQR System to submit data for these measures has reduced the number of ways ASCs must report quality measure data. We urge CMS to continue to streamline data submission methods by

re-evaluating the requirement to use NHSN for reporting the COVID-19 Vaccination measure, which continues to pose challenges for ASCs. We suggest CMS move data collection for the COVID-19 Vaccination measure to the HQR System by replicating only the NHSN data entry fields essential to calculating the measure. This change would streamline submission methods and be more efficient for ASCs. CMS could in turn share the data with CDC.

### C. Modify the OAS CAHPS Survey and Requirements

We fully support the use of the OAS CAHPS survey as a standardized instrument focusing on the patient's experience of care. However, implementing the OAS CAHPS survey is expensive. For many ASCs, these costs will be more than the 2% payment update penalty for failing to meet ASCQR Program requirements.

One method of reducing costs and improving response rates would be to shorten the OAS CAHPS in a way that does not sacrifice key information. A recent study of the CAHPS Clinician and Group Survey found that the *Provider Communication* (6-items) and *Access* (5-items) domains could be reduced to as few as two-items each and *Office Staff* (2-items) could be reduced to a single item without a substantial loss in reliability or content.[37] There are also opportunities to streamline the OAS CAHPS without losing important information and steps should be taken to do so.

### D. Voluntary Reporting for the Risk Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO–PM) in the ASC Setting Measure Until Major Reductions in Burden Are Incorporated

We believe in the value of patient reported outcomes. However, as currently specified, the THA/TKA PRO-PM measure is complex and will pose implementation challenges that will be very difficult to overcome. CMS should make reporting voluntary until such time as a simplified PRO-PM can be put in place. We encourage CMS to test the measure in the ASC setting. Results could be used to guide modifications to the measure specifications, measure methodology, performance expectations and data submission requirements. We would be happy to work with CMS's measure development contractor in this effort.

## VI. Revision of the ASCQR Program Claims Threshold is Needed

Currently, ASCs with fewer than 240 Medicare FFS claims (primary plus secondary payer) per year during a reporting period are not required to participate in the ASCQR Program for the subsequent reporting period, such that an ASC with fewer than 240 Medicare FFS claims in 2024 would not be required to submit 2025 data for the CY 2027 payment determination.

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[37] Stucky BD, Hays RD, Edelen MO, Gurvey J, Brown JA. Possibilities for Shortening the CAHPS Clinician and Group Survey. Med Care. 2016 Jan;54(1):32-7. doi: 10.1097/MLR.0000000000000452. PMID: 26536332; PMCID: PMC10363959.

Small ASCs with relatively low volume are being increasingly stretched by ASCQR Program requirements. To help mitigate this, CMS should propose to raise the claims threshold in the next rulemaking cycle. Small ASCs should not be penalized for lacking sufficient resources to comply with costly Program requirements.

## VII. Proposed Modification of the Immediate Measure Removal Policy in Favor of an Immediate Measure Suspension Policy

When measures have not been thoroughly vetted and tested prior to CMS adoption in quality reporting programs, it is possible that unintended consequences impacting patient safety can result from the use of the measure. In the past, CMS established and codified a process for the immediate removal of ASCQR Program measures if evidence were to develop demonstrating that a measure raises patient safety concerns.

Rather than immediately removing such a measure from a quality reporting program, CMS is now proposing that when there is evidence continued use of a measure may harm patients, immediate action would be taken to suspend the use of the measure. The agency proposes to notify ASCs and the public of its decision to suspend a measure through standard communication channels, such as program-specific listservs and program guidance currently housed on the Quality Reporting Center website.

After suspension of data collection and reporting, CMS would then propose the potential removal of the measure in question and seek public comment in the next feasible rulemaking cycle. The agency believes this would increase transparency and the public's voice in decision-making.

CMS proposes to implement this policy change and to codify its use through revised regulatory text beginning in CY 2025. The agency has proposed the same changes to the Hospital OQR Program.

We support this proposal. If the proposed Screening for Social Drivers of Health (SDOH) measure is adopted in the ASCQR Program without removing the requirement to screen for interpersonal safety, we anticipate this policy will be required to address the resultant risks to patient safety.

## VIII. Public Reporting of ASCQR Program Data

CMS must improve the public reporting of ASCQR Program data. The development of the Facility Compare Dashboard on the Quality Reporting Center website has been helpful, and we appreciate the information made available there. However, this website is not widely known to patients and caregivers, who should be a primary focus of efforts to share this data. Medicare beneficiaries and consumers are most likely to look for information about quality of care on the CMS Care Compare website. It is discouraging that ASC quality data are still not available there despite our repeated requests. Until ASC data is added to Care Compare, the agency should make it easier for consumers to locate and interpret the ASC data on the data.cms.gov website.

ASCs perform the majority of outpatient surgical and procedural services in the United States, so it is important for consumers to have ready access to ASC data. The agency is solely responsible for ensuring this information is shared in a manner that is readily accessible and in a form that is both understandable and helpful to the public. CMS must make a serious effort to improve its public reporting of ASC data. The agency should develop clear and intuitive paths to ASC quality data on the data.cms.gov website while also making strides toward displaying the data on the Care Compare site.

**IX. Closing Remarks**

Participation in the ASCQR Program has become increasingly expensive. Mandatory reporting of the OAS CAHPS survey is imminent and is proving very costly. The challenges that will be posed by the THA/TKA PRO-PM measure are looming in the future. Now ASCs are facing the potential for significant additional burdens if the FCHE measure is adopted without modification. We are concerned the Program is near the point at which some ASCs will find the costs of participation exceed the two percent payment update sacrificed by not meeting reporting requirements. We believe the Program is important and want to see high levels of engagement maintained into the future. CMS must carefully consider the balance between participation and burden as it determines which of the proposed requirements will be adopted for the Program.

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Thank you for considering these comments. We look forward to continuing our dialogue with CMS regarding the ASCQR Program and would be happy to provide additional information at your request.

Sincerely,

*Kathy Wilson*

Kathy Wilson, RN, MHA
Executive Director
ASC Quality Collaboration

## Appendix A:
## Current Participants in the Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory Health Care
Accreditation Commission for Health Care
Ambulatory Surgery Center Association Foundation
AMSURG
Association of periOperative Registered Nurses
California Ambulatory Surgery Association
ECRI
Florida Society of Ambulatory Surgery Centers
GI Alliance
HST Pathways
Indiana Federation of Ambulatory Surgery Centers
Kaiser Permanente
Merritt Healthcare
New Jersey Association of Ambulatory Surgery Centers
NueHealth
NVision Eye Centers
Michigan Ambulatory Surgery Association
New York State Association of Ambulatory Surgery Centers
Outpatient Ophthalmic Surgery Society
Physicians Endoscopy
Proliance Surgeons
QUAD A
Regent Surgical Health
SCA Health
Sovereign Healthcare
Specialist Management Solutions
Surgery Partners
Surgery Ventures powered by HCA Healthcare
Surgical Management Solutions
Surglogs
Tenet Healthcare/United Surgical Partners International
The Joint Commission
US Heart and Vascular