Alliance for Screening Measurement Modernization

Series of Briefs

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Acknowledgements

The Alliance for Screening Measurement Modernization (ASMM) series of briefs were developed through the collective efforts of members of the ASMM's Industry and Quality Councils. Members of the ASMM Councils represent clinicians, screening technology industry leaders, patient advocates, and other nonprofit organizations and experts focused on healthcare quality measurement. ASMM Quality Council members include FasterCures of the Milken Institute, Friends of Cancer Research, the National Kidney Foundation, and URAC, alongside contributors participating in their individual capacity, including Dana Gelb Safran, Sc.D., Dheerendra Kommala, M.D., Lisa Satterfield, M.S., M.P.H., C.A.E., C.P.H., and Sarah Duggan Goldstein, Dr.P.H., M.P.H. A government contractor in the measurement space is an additional contributor. ASMM Industry Council members include Cepheid, Freenome Holdings, Inc., Geneoscopy, Guardant Health, Hologic, Natera, and the Prevent Cancer Foundation, representing the patient voice. From Rubrum Advising, Lee A. Fleisher, M.D., M.L., Nancy Foster, Matthew Fleisher, J.D., M.P.H., Tristen Tellman, Ph.D., and Eleanor Wolfe, M.P.H. contributed to the drafting of these reports.

Executive Summary

The Alliance for Screening Measurement Modernization (ASMM) was convened to close the gap between rapidly evolving screening technologies—which may offer greater accuracy or more patient-centered approaches—and the slow adoption of these technologies into the quality measures used to assess physician, clinic, and health plan performance. This cross-sector initiative operates through two separate but coordinated councils: a Quality Council comprised of representatives from guideline setting organizations, clinicians, measure developers and stewards, and other nonprofit stakeholders, and an Industry Council comprised of diagnostic innovators and a patient advocacy organization. The ASMM met from June through December 2025 to develop the ASMM series of briefs and design a practical framework for more timely measure modernization.

Background

The United States Preventive Services Task Force (USPSTF) issues evidence-based recommendations on preventive services, including diagnostic screening tests. USPSTF recommendations are influential but resource intensive; updates often take years, meaning new FDA cleared or approved screening technologies often wait long periods of time before formal USPSTF review and update. Many measure developers and stewards voluntarily align their screening quality measures with USPSTF updates, leading to a delay in the modernization of measures.

Quality measures are key aspects of how health plans evaluate performance, reward providers, and structure value-based contracts. When quality measures are not updated to reflect current standards of care, providers may not be incentivized to use new technologies, even though they may offer advantages. This resulting misalignment between regulatory approval, quality measurement, and clinical practice can lead to consequences for patients and decreased access to modern screening modalities.

The ASMM Framework

The ASMM Framework is intended to establish an evidence threshold for measure developers and stewards to determine when to recognize a new screening modality within existing quality measures, especially where USPSTF updates are delayed.

A key component of the ASMM Framework is the Decision Tree included in Brief 2, that describes when a measure update should be considered. The Decision Tree provides the following steps to help determine whether to include a new technology in a screening measure:

- *Step 1: Is the technology covered in a USPSTF "A" or "B" recommendation?*
  If the modality is in a USPSTF "A" or "B" recommendation, measure developers and stewards may treat that as a default trigger to consider updating the measure. "C" ratings call for case-by-case evaluation, and "D" and "I" ratings are generally excluded unless new evidence supports inclusion.
- *Step 2: Is the technology included in a CMS National Coverage Determination (NCD)?*
  If not in an "A" or "B" recommendation, measure developers and stewards should consider if CMS has issued an NCD. A positive NCD alone provides sufficient evidence to justify considering a measure update.
- *Step 3: Has the USPSTF initiated an update to their recommendation?*
  If there is no NCD, measure developers and stewards should determine if the USPSTF has started an update to their recommendation, and, if so, wait up to 18 months from the posting of the draft research plan before acting independently.
- *Step 4: Additional evidence for measure reconsideration*
  If neither a USPSTF recommendation nor NCD provides guidance, measure developers and stewards are directed to rely on robust independent evidence (such as meta-analyses or robust guidelines), ideally seeking at least two strong, conflict-free sources.

Because later steps in the Decision Tree rely on guidelines and evidence from various sources, the ASMM recommends using established standards and independent rating tools to determine guideline quality; measure developers and stewards are asked to focus on transparency and evidentiary rigor. When two or more highly rated guidelines or meta-analyses from different organizations endorse the same screening modality, that may serve as a strong signal that a measure update is appropriate.

Implementation and Authorities

Brief 3 outlines how key actors can operationalize the Framework:

- **Device manufacturers**: Use the Framework to determine when evidence thresholds are met and submit structured, well-supported requests for measure inclusion or updates.
- **Measure developers and stewards**: Apply the Framework on an ongoing basis, accept evidence-based requests year-round, and initiate formal reconsiderations within six months when thresholds are met, advancing qualified updates for endorsement and CMS adoption.
- **CMS**: Use statutory and contractual authority to ensure measures in federal programs reflect current evidence and covered technologies.

- **USPSTF**: Meet statutory expectations to review and update recommendations at least every five years, use early topic updates when appropriate, and publish schedules and evidence queues to enable measure alignment.
- **HHS**: Consider regulatory guidance that sets expectations for timeliness and evidentiary standards across quality programs.
- **Congress**: Provide resources and oversight to support timely USPSTF reviews and encourage CMS and HHS to hold measure stewards accountable for updating measures in line with current evidence.

Conclusion

Taken together, the ASMM series of briefs offers measure developers and stewards a practical, evidence-based framework to ensure national screening measure alignment with modern technologies. By translating existing evidence and regulatory decisions into clear triggers for action, unnecessary delays between innovation, measurement, and clinical adoption can be reduced. For Congress and other stakeholders, supporting the uptake and use of this framework can help ensure that federal quality programs promote timely access to preventive health care.

Brief 1: Framing the Problem

The USPSTF

The United States Preventive Services Task Force ("USPSTF" or "the Task Force") is an independent, non-governmental panel of experts in prevention and evidence-based medicine that evaluates clinical preventive services, such as diagnostic screening services, and issues recommendations. Established in 1984, the USPSTF's mission is to advance population health by systematically reviewing scientific evidence and assessing the balance of benefits and harms of preventive services. Since 1998, the Agency for Healthcare Research and Quality (AHRQ), within the U.S. Department of Health and Human Services, has been statutorily directed by Congress to convene and support the Task Force.[1] The USPSTF plays a critical role as the arbiter of which preventive services should be offered by Affordable Care Act compliant plans. The Task Force's impact since its establishment has been significant; a 2022 report from the U.S. Department of Health and Human Services' Assistant Secretary for Planning and Evaluation indicated that more than 150 million individuals with private insurance, 20 million Medicaid adult expansion enrollees, and 61 million Medicare beneficiaries can benefit from preventive services offered through the Affordable Care Act.[2]

Implications of USPSTF Recommendations

Each recommendation issued by the Task Force is accompanied by a letter grade (A, B, C, D, or I statement) reflecting the strength of evidence and the magnitude of net benefit for different populations. "A" or "B" recommendations indicate moderate-to-high certainty of moderate-to-substantial net benefit and must be covered by most health plans without cost sharing, as codified by the 2010 Affordable Care Act.[3] This linkage between evidence-based recommendations and mandatory coverage has established the USPSTF as an influential entity in shaping preventive care policy and uptake in the United States.

As detailed in Title IX of the Public Health Service Act, the duties of the Task Force include reviewing and updating its recommendations at least once every five years, though delays are common, meaning that innovation sometimes moves faster than the USPSTF can respond.[3]

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[1] "About the USPSTF," *U.S. Preventive Services Task Force,* n.d. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf

[2] "Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act," *U.S. Department of Health & Human Services: Assistant Secretary for Planning and Evaluation: Office of Health Policy,* January 11, 2022. https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf

[3] "Procedure Manual Appendix I. Congressional Mandate Establishing the U.S. Preventive Services Task Force," *U.S. Preventive Services Task Force,* n.d. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual/procedure-manual-appendix-i

Consequently, emerging screening technologies may outpace the Task Force update cycle, creating gaps between coverage requirements and available innovations in clinical practice. When new screening modalities are not promptly incorporated into USPSTF recommendations, providers may be hesitant to adopt them due to uncertainty about measure credit or reimbursement or due to potential patient cost-sharing implications, inadvertently hindering their broader adoption and depriving patients of access to screening technologies that have the potential to improve health outcomes.

Relationship to Quality Measures

Measure developers and stewards of quality measures that are included in various Centers for Medicare and Medicaid Services (CMS) quality programs have historically waited for USPSTF recommendations before updating their measures. When the USPSTF makes recommendations for established screening programs, measure developers and stewards typically move swiftly to incorporate them into their quality measurement sets. This alignment supports cohesive national standards but has also historically created unintended bottlenecks when USPSTF updates lag behind biomedical innovation.

Screening measures appear in multiple CMS programs and are developed by a diverse group of organizations, including the American Medical Association (AMA) and medical specialty societies. Additionally, CMS and the National Committee for Quality Assurance (NCQA) play key roles in operationalizing USPSTF recommendations through performance measures embedded in programs such as the Medicare Advantage Star Ratings, Medicaid Core Sets, and the Quality Rating System for Marketplace plans.[4] NCQA develops, maintains, and publicly reports the Healthcare Effectiveness Data and Information Set (HEDIS) measures: a set of standardized performance measures used to evaluate and compare the quality of health plans, which includes the majority of screening performance measures.[5] Through use of HEDIS measures, health plans can structure performance-based contracts and offer financial rewards to providers who meet or exceed quality targets.[6] NCQA currently maintains more than 90 HEDIS measures across six domains: Effectiveness of Care, Access and Availability, Experience of Care, Utilization and Risk-Adjusted Utilization, Health Plan Descriptive Information, and Measures Collected Using Electronic Clinical Data Systems. Performance data from HEDIS measures is

[4] "Reporting Requirements for HEDIS® Measurement Year (MY) 2023, HOS, and CAHPS® Measures, and Information Regarding HOS and HOS-M for Frailty," *Centers for Medicare & Medicaid Services,* n.d. www.cms.gov/files/document/2024reportingrequirementsforhedishosandcahps5152023g.pdf

[5] "HEDIS and Performance Measurement," *National Committee for Quality Assurance,* 2023. www.ncqa.org/hedis/

[6] "Incentivizing Quality Improvements: Using HEDIS to Align and Improve Health Care Quality," *National Committee for Quality Assurance,* n.d. https://www.ncqa.org/wp-content/themes/ncqa-org/css/images/landing-employer-toolkit/pdf/NCQA-HPA-IncentivizingQuality-WEB.pdf

collected and used by CMS to identify opportunities for improvement, monitor the success of quality improvement initiatives, and track performance over time.[7]

Limitations of the Current Process

Although the USPSTF's method for developing recommendations is rigorous and transparent, the process faces notable operational limitations.[8] Ideally, the Task Force would be sufficiently resourced to conduct reviews in a timely manner, however, due to the complexity of the analysis, limited staffing and available support, each topic review commonly takes nearly two years to complete. As a result, innovations such as FDA-approved screening technologies may wait years before formal evaluation. **Table 1 (see appendix)** outlines the reality of the timeline from draft research plan to USPSTF recommendation finalization. **Table 2 (see appendix)** provides a breakdown of the time between review cycles for a collection of example USPSTF recommendations.

Because there is no statutory or regulatory requirement for quality measure developers to await a USPSTF update before revising their measures, developers technically retain discretion to act on their own. However, absent a standardized framework for how to update measures responsibly in the interim, most organizations defer to USPSTF guidance, producing significant misalignment between scientific progress and performance measurement.

Screening Quality Measures

Provider organizations can use quality measures to assess care performance in their health systems. Screening quality measures are also used by some payers to incentivize performance in different value-based performance programs and by some oversight bodies to inform their reviews. Given their significant implications, ensuring that quality measures are updated to reflect the latest standards of care is essential. If measures are not updated to include technologies needed for modern care delivery, new care technologies and screening modalities (which may offer improved access or performance characteristics) risk becoming excluded from diagnostic paradigms as providers continue to use more dated tools and techniques to comply with screening measures. From both an operational and public health perspective, it is therefore of the utmost importance that screening measures are designed, maintained, and updated expediently, accurately, and efficiently.

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[7] "Healthcare Effectiveness Data and Information Set (HEDIS)" *Centers for Medicare & Medicaid Services,* November 28, 2023. www.cms.gov/medicare/enrollment-renewal/special-needs-plans/data-information-set

[8] "Procedure Manual," *U.S. Preventive Services Task Force,* April 2023. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual

The Alliance for Screening Measurement Modernization (ASMM)

To address these systemic challenges, Rubrum Advising convened the Alliance for Screening Measurement Modernization (ASMM): a cross-sector initiative designed to ensure that currently endorsed quality measures utilized by CMS and other bodies related to screening are updated in step with innovation. The Alliance's mission was to establish a transparent, evidence-oriented framework to enable measure developers to modernize national screening quality measures in alignment with regulatory standards and evolving best practices. Updated measures are vital, as these benchmarks affect care delivery, provider reimbursement, and the timely adoption of new screening tools.

The Alliance was comprised of two independent councils:

- The **Quality Council** was made up of representatives from guideline-setting bodies, clinician representatives, quality measure developers and stewards, and other nonprofit organizations. This council developed the framework and served as the final decision-maker.
- The **Industry Council** consisted of representatives from a patient advocacy organization and diagnostic companies at the forefront of developing innovative screening technologies to support more accurate, accessible, and timely diagnoses. This group provided input and expertise in an anonymized manner to the Quality Council. The Industry Council was led by a Steering Committee, who set the direction of the council.

The councils met independently from June to December 2025, reviewing current lag patterns across USPSTF, CMS, and NCQA processes and developing a structured model to accelerate measure updates. The Industry Council provided input on key considerations and proposed recommendations to the Quality Council. Any differing opinions were documented. The Alliance's collective objective was to ensure timely, evidence-based adoption of new screening technologies, balancing scientific rigor with pragmatic operational guidelines. Through this process, the Alliance sought to build a roadmap for proactive, multi-stakeholder collaboration to modernize screening quality measurement systems and improve patient access to preventive care innovations in the United States.

Appendix

Table 1. *Timeline from draft research plan to final recommendation for USPSTF recommendation updates*

USPSTF Recommendation	Draft Research Plan Posted for Public Comment	Final Research Plan Published	Draft Recommendation Issued	Final Recommendation Issued	Total Time from Draft Research Plan Posted for Public Comment to Final Recommendation
Screening for Breast Cancer (2016 recommendation)	November 14, 2013	July 17, 2014	April 21, 2015	January 11, 2016	25 months
Screening for Breast Cancer[9] (current recommendation)	January 21, 2021	May 6, 2021	May 9, 2023	April 30, 2024	39 months

[9] Breast Cancer: Screening, USPSTF, April 30, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening

Screening for Cervical Cancer (2018 recommendation)	May 28, 2015	October 29, 2015	September 12, 2017	August 21, 2018	38 months
Screening for Cervical Cancer[10] (current recommendation)	October 28, 2021	March 17, 2022	December 10, 2024	Not yet finalized	53 months (ongoing)
Screening for COPD[11]	July 2, 2020	October 8, 2020	November 2, 2021	May 10, 2022	22 months
Screening for Lung Cancer[12] (current recommendation)	May 3, 2018	August 16, 2018	July 7, 2020	March 9, 2021	34 months

[10] Cervical Cancer: Screening: USPSTF, December 3, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/draft-update-summary/cervical-cancer-screening-adults-adolescents

[11] Chronic Obstructive Pulmonary Disease: Screening, USPSTF, May 10, 2022. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chronic-obstructive-pulmonary-disease-screening

[12] Lung Cancer: Screening, USPSTF, March 9, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening

Screening for Colorectal Cancer	January 3, 2019	May 16, 2019	October 27, 2020	May 18, 2021	28 months

Table 2. *Time between USPSTF recommendation updates*

USPSTF Recommendation	**Final Recommendation Statement**	**Elapsed time (y,m)**
Screening for Colorectal Cancer	1/1/1996*	n/a
	6/13/2002*	6y 5m
	10/15/2008*	6y 4m
	6/15/2016	7y 8m
	5/18/2021	4y 11m
Screening for Lung Cancer	1/1/1996*	n/a
	5/15/2004*	8y 4m
	12/31/2013	9y 7m
	3/9/2021	7y 2m
Screening for Breast Cancer	1/1/1996*	n/a
	9/3/2002*	6y 8m
	12/15/2009*	7y 3m
	1/11/2016	6y 1m
	4/30/2024	8y 3m
Screening for Cervical Cancer	01/01/1996*	n/a
	01/07/2003*	7y 0m
	03/15/2012	9y 2m
	08/21/2018	6y 5m
	TBD (Draft statement 12/10/2024)	7y 7m and counting

**indicates pre-ACA (prior to 2010)*

Brief 2: The Framework

Background and Rationale

Rubrum Advising convened the Alliance for Screening Measurement Modernization (ASMM) with the mission to establish a transparent, evidence-oriented framework to enable measure developers to modernize currently-endorsed national screening quality measures in alignment with regulatory standards and evolving best practices. Central to these efforts is a thorough understanding of current decision-making and guideline-setting authorities of key bodies, including those of the United States Preventive Services Task Force (USPSTF), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS). The ASMM considered how to streamline more timely updates to quality measures used to assess providers and health plans, placing a strong emphasis on leveraging published evidence-based reviews and guidelines. The ASMM was explicit that the proposed process is intended only to help establish an evidence threshold for measure developers to determine when to include a new screening modality in currently-endorsed quality measures and is not meant to influence coverage determinations or insurers' cost-sharing requirements.

The USPSTF is an independent, non-governmental panel of experts in prevention and evidence-based medicine that evaluates clinical preventive services, such as diagnostic screening services, and issues recommendations. For screening recommendations with an "A" or "B" rating, there is zero cost-sharing for patients who undergo included screening tests in most health plans, in accordance with the Affordable Care Act, facilitating broad access for patients. USPSTF's method for developing recommendations is rigorous, but limited resources and competing priorities mean new FDA cleared or approved screening tests may wait years before formal evaluation and inclusion in updated recommendations.[13] Many measure developers voluntarily align the timing of their measure updates with updated USPSTF recommendations, absent a clear standardized process for responsible interim measure update, which can lead to a lag between biomedical innovation and use in clinical practice.

Consider the following hypothetical scenario as an illustration of the problem: bladder cancer screening receives an "A" rating from the USPSTF in the future based upon a blood-based biomarker, and a quality measure referencing this screening modality is rapidly adopted. Two years later, a urine-based liquid biopsy test receives FDA approval and CMS coverage (through a National Coverage Determination (NCD)). However, because the USPSTF does not plan to

[13] Procedure Manual, United States Preventive Services Taskforce, n.d. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual

update its recommendation for several more years, quality measures still only recognize the blood test. As a result, clinicians rarely order the new urine-based test, despite coverage by Medicare and reimbursement, since the ordering physician and health plan may receive a lower quality score on the quality measure. Further, patients may choose not to be screened if they are unwilling to undergo blood-based screening. This mock scenario underscores how misalignment between regulatory review, national coverage, and quality measurement can delay patient access to new, evidence-based screening technologies.

The Framework

Purpose of this Framework

The ASMM Framework was created to give measure developers a clear evidence threshold to determine when to consider an update to screening quality measures, particularly in situations where the USPSTF has not yet issued an updated recommendation. The framework provides a structured set of signals and triggers to guide decision-making and ensure there is sufficient, credible evidence to incorporate an FDA cleared or approved screening technology into federal measurement programs efficiently and responsibly.

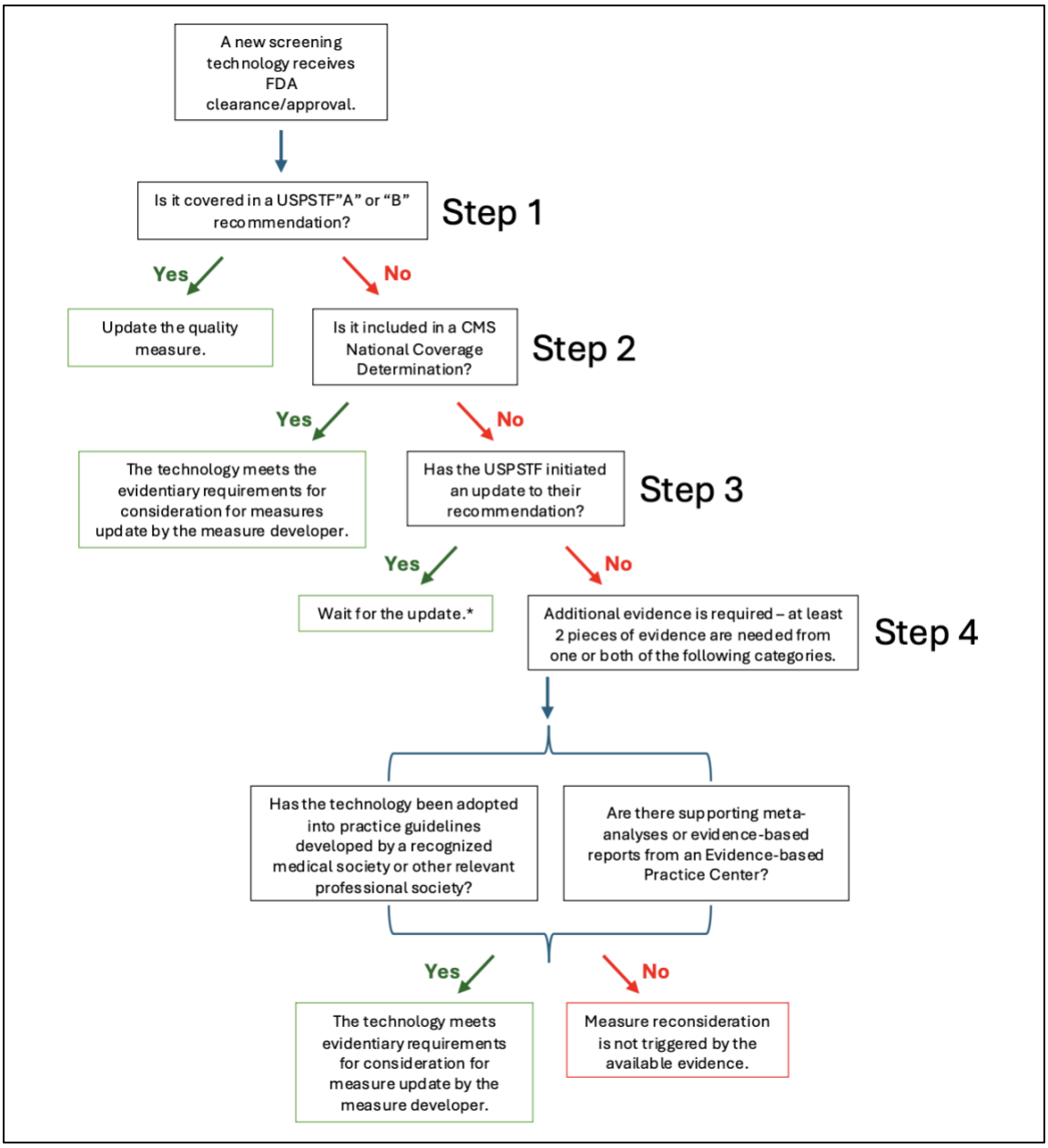
By applying this framework, measure developers gain a consistent evidence-based standard for assessing whether technologies cleared or approved by the FDA should be considered for inclusion into existing measures. Importantly, the final decision to update a measure still rests with the measure stewards. This process reduces reliance on delayed USPSTF recommendations, promotes alignment with regulatory and clinical standards, and minimizes unnecessary delays in promoting patient access to safe, validated screening tools without the need for statutory or regulatory action.

The Decision Tree

The decision tree (**Figure 1**) provides a straightforward, step-by-step visual guide for measure developers to determine when and how to consider updating screening measures. At each step, developers should evaluate available information to determine whether there is sufficient evidence for a measure update to be considered.

In evaluating the potential scope of this framework, it was determined that the framework should apply only to new screening technologies that have received FDA clearance or approval. Laboratory-developed tests (LDTs), which do not go through a formal regulatory pathway, are intentionally excluded from the proposed process and are beyond the scope of this framework.

Figure 1. The Decision Tree



*The ASMM recommends an 18-month waiting period from publication of a USPSTF draft research plan to the final recommendation. If no final recommendation is issued within 18 months, developers may proceed down the decision tree

The following is a step-by-step approach to the process:

STEP 1: Is the technology covered in a USPSTF "A" or "B" recommendation?

If the technology is covered by a USPSTF "A" or "B" recommendation, measure developers should treat this as an automatic trigger to consider initiating a measure update. "A" or "B" designations indicate that there is a high or moderate certainty that the screening

recommendation provides a substantial or moderate net clinical benefit, making inclusion straightforward within national measurement programs. USPSTF advises that screening recommendations that receive a USPSTF "C" rating should be selectively offered or provided to individuals based on professional judgment and patient preferences, as the net benefit is considered small. In these cases, measure developers should carefully weigh the evidence, consider variability in clinical practice, and assess whether measure update is warranted. To be clear, the ASMM is not proposing changes to the USPSTF A and B recommendations themselves. Our focus is on whether a specific screening modality should be recognized as meeting the screening requirement within the current USPSTF framework.

For screening recommendations rated "D" or "I" by the USPSTF, the ASMM recommends that measure developers do not consider a measure update unless there is new evidence that was not available to the USPSTF at the time of their review. Screening services rated "D" by the USPSTF indicate that "there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits." An "I" rating reflects that "the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined." Given these definitions, technologies or services with a "D" or "I" rating fall outside of the appropriate scope of this framework, except when new evidence prompts reassessment of the technology in question.

If the technology has not been reviewed by the USPSTF, or if there is substantive new evidence since the USPSTF's last assessment and no update has been initiated, the measure developer should follow the "no" arrow and continue to **Step 2** in the tree.

STEP 2: Is the technology included in a CMS National Coverage Determination?

At this stage, measure developers should determine whether a CMS NCD has been published relevant to the FDA cleared or approved technology. An NCD is viewed by the ASMM as independently sufficient evidence for the measure developer to consider a measure update, as it represents a rigorous and transparent federal decision based on systematically vetted clinical evidence. As part of the NCD process, CMS evaluates the available studies and literature to determine that the item or service is "reasonable and necessary" for the diagnosis or treatment of illness or injury, setting a national standard within the Medicare population. The evidentiary review process often incorporates independent technology assessments and advisory committee input, with opportunities for public comment, ensuring that NCDs meet high scientific benchmarks before becoming binding policy.

For measure developers, an NCD provides a strong, defensible basis for including technologies in currently-endorsed quality measures, as this aligns with widespread clinical adoption and

consistent reporting across the Medicare program. ASMM does not assert that inclusion in the quality measure as a satisfactory screen requires commercial insurers to cover with or without cost-sharing in non-federal programs.

If there is no NCD, the measure developer should advance to **Step 3** of the decision tree.

STEP 3: Has the USPSTF initiated an update to their recommendation?

The next step for measure developers is to determine whether the USPSTF has initiated an update to its recommendation for the relevant screening condition. If the USPSTF has already begun its review process, the developer should wait for the updated USPSTF recommendation or for an NCD to cover the technology before updating their measures to ensure alignment.

That being said, the ASMM expressed concern that measure developers could wait multiple years to update their measure while the USPSTF update process is slowly underway. To balance timelines with deference to USPSTF guidance, the ASMM recommends an 18-month waiting threshold from when USPSTF issues a draft research plan to the publication of the final USPSTF recommendation. If after 18 months no final recommendation has been published, developers may proceed down the decision tree to evaluate whether a measure update is warranted.

This threshold was based on typical timelines observed in USPSTF review cycles, which often experience known delays. For example, the interval from posting a research plan for public comment to issuing the final recommendation recently spanned 39 months for breast cancer screening, 34 months for lung cancer screening, and 53 months and counting for cervical cancer screening, according to the USPSTF's most recent recommendations for these diseases.[14, 15, 16] Adopting this 18-month limit ensures a balance between respecting federal guidance and preventing the stagnation of innovation within quality measurement systems. Importantly, if a new screening modality has been FDA cleared or approved just after the publication of a new USPSTF final research plan, it is unreasonable to expect that the recommendation would address the new test, and the waiting period does not apply. In either scenario, the measure developer should move down the decision tree to **Step 4**.

Several members of the Industry Council expressed the desire that the time since FDA clearance or approval of the new screening modality should also be considered as part of the

[14] Breast Cancer: Screening, USPSTF, April 30, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening
[15] Lung Cancer: Screening, USPSTF, March 9, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening
[16] Cervical Cancer: Screening, USPSTF, December 4, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/draft-update-summary/cervical-cancer-screening-adults-adolescents

waiting threshold. While we have not included that timeline in this framework, the ASMM believes this could be a valuable consideration.

STEP 4: Additional evidence for measure reconsideration

When a recommendation from the USPSTF or CMS via an NCD is not available, measure developers can rely on robust sources such as meta-analyses, evidence-based practice center reports, or high-quality medical guidelines to support the inclusion of new technologies in quality measures. It is critical that these sources are free of conflicts of interest (meta-analyses or systematic reviews funded or sponsored by device manufacturers should not be considered) as the potential for bias may compromise the integrity of the evidence.

The ASMM recommends that a measure update be considered if there are at least two substantive guidelines and/or research syntheses available, ensuring a strong evidentiary review for potential updates. However, members of the ASMM held varying views on the appropriate threshold: some suggested that, in exceptional circumstances such as rare or difficult-to-assess diseases, a single high-quality source, such as a professional guideline, might suffice. Others advocated for requiring three independently published research syntheses or guidelines to justify a measure update. Despite these differences, there was consensus that measure developers should consider all available research and guidelines in their review. Additionally, members of the ASMM stated their desire to include other government body assessments, such as the Health Resources and Services Administration Women's Preventive Services Initiative, when available, in the evidence for measure update considerations. This approach, incorporating diverse and high-quality sources, strengthens the measure update process and helps align it with the highest standards for evidence-based decision-making.

Tools to Evaluate Trustworthy Guidelines

To evaluate the trustworthiness of a clinical practice guideline, developers are encouraged to use the Institute of Medicine's (IOM's) "Clinical Practice Guidelines We Can Trust" standards, focusing on transparency, conflict-of-interest management, evidence-based foundations, external review, and commitment to timely updating. These standards, endorsed by the ASMM, ensure that a guideline is trustworthy and can be relied upon as a legitimate reason to update a measure. Using the GRADE framework (Grading of Recommendations, Assessment, Development, and Evaluations) may add an additional layer of rigor, requiring that recommendations be explicitly tied to underlying evidence and that benefits, risks, and certainty are all systematically considered.

Given the fast pace of change in clinical guideline development, it is unrealistic to expect measure developers to keep up with every new or updated guideline on their own. To address this challenge, the ASMM recommends leveraging tools like the ECRI Guidelines Trust, which

serves as an independent evaluator of guideline trustworthiness. ECRI, as one of the Agency for Healthcare Research and Quality's designated Evidence-based Practice Centers, systematically assesses guidelines based on the IOM standards for trustworthy guideline development.

In ECRI's review process, guidelines are scored from one to five stars in domains such as the strength and summary of evidence, strength of recommendations, and conflict-of-interest management.[17, 18] For clinical practice guidelines that contain screening interventions and technologies, ECRI recommends that the following standards be considered in guideline review: literature search, study selection, and evidence synthesis. A rating of four or more stars in these domains gives measure developers high confidence in the underlying evidence and independence of the guidance. When a new screening technology is endorsed in guidelines from reputable organizations, this provides a strong, objective signal that a measure update is likely warranted. This approach helps measure developers efficiently identify and prioritize technologies for inclusion into quality measures. If two or more disparate bodies have both included the new screening technology in their updated guideline, and they receive star ratings of four or greater on these criteria from ECRI, it is a strong signal to the measure developers that measure update might be warranted.

ASMM recommends using the ECRI Guidelines Trust for those guidelines that have been assessed and have a scorecard. If ECRI has developed a Guideline Profile, but no Trust Scorecard for a specific guideline, ASMM recommends that measure developers conduct their own analysis of the guideline, utilizing the standards of the IOM's "Clinical Practice Guidelines We Can Trust."

In Conclusion

The ASMM framework provides guidance for modernizing national screening quality measures in a rapidly changing evidence and regulatory environment. By setting clear pathways for integrating new FDA cleared or approved screening technologies into federal quality measures, even when USPSTF recommendations are delayed, the framework offers developers a defensible, trustworthy, evidence-based standard for updating measures. Crucially, the inclusion of CMS NCDs as a trigger ensures that technologies already deemed reasonable and

[17] Jue, J. J., Cunningham, S., Lohr, K., Shekelle, P., Shiffman, R., Robbins, C., Nix, M., Coates, V., & Schoelles, K. Developing and Testing the Agency for Healthcare Research and Quality's National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards (NEATS) Instrument, *Annals of Internal Medicine*, March 19, 2019, *170*(7), 480–487. https://doi.org/10.7326/m18-2950

[18] We recognize that ECRI has a range of business areas, and our focus is specifically on the ECRI Guidelines Trust and its associated TRUST Scorecard system for evaluating clinical practice guidelines.

necessary by Medicare are promptly reflected in measurement systems, supporting rapid and consistent coverage for beneficiaries.

Taken together, these reforms foster timely access to innovative screening tools, promote alignment with trusted clinical standards, and help uphold the highest standards of transparency and rigor in quality measurement.

Brief 3: Implementation of the Alliance for Screening Measurement Modernization to Update Quality Measures

Background

Scientific advances have led to the development of screening tests that can detect many conditions and are commonly used in preventive care; however, access is often gated by a myriad of barriers in the screening ecosystem. The United States Preventive Services Task Force (USPSTF) evaluates these services and issues graded recommendations for clinicians and eligible Americans, such as when to begin screening. When USPSTF assigns an "A" or "B" rating, most health plans cover the service with no cost-sharing. The Centers for Medicare & Medicaid Services (CMS) determines coverage and conditions of use in their programs, and groups such as the National Committee for Quality Assurance (NCQA) and medical specialty societies translate these standards into quality measures used for public reporting and payment. These measures track how often or how many patients receive recommended screening and often drive financial incentives for providers. Despite a statutory requirement, USPSTF updates and recommendations are frequently delayed, potentially resulting in outdated quality measures that do not include new screening technologies. This often occurs because measure developers have historically waited for USPSTF guidelines to be updated before initiating a measure update themselves. Until quality measure updates occur, plans and clinicians may not receive credit for using newer evidence-based tests, limiting patient access to innovation and prolonging preventable gaps in early detection and treatment.

Implementation of the Framework

The Alliance for Screening Measurement Modernization (ASMM) Framework, described in Brief 2, gives device manufacturers, measure developers and stewards, federal agencies, and Congress a common playbook of potential thresholds to add new screening technologies into quality measures. It offers a transparent way to act on robust evidence, even when USPSTF has not yet begun an update to its recommendations by setting a minimum evidence threshold for considering a technology as an acceptable screening option in national quality measurement programs.

To operationalize the ASMM Framework, each stakeholder group should take the following actions:

- **Device Manufacturers:** Apply the ASMM Framework to determine evidence sufficiency. When thresholds are met, submit structured, well supported requests for measure inclusion or update to measure developers and/or stewards.

- **Measures Developers and Stewards (NCQA, specialty societies):** Continuously apply the ASMM Framework to identify measure update needs. Accept and review evidence-based requests year-round using transparent procedures. Within six months of notification that the evidence threshold has been met, initiate formal reconsideration of the measure, taking into account any necessary budgeting and testing, and advance qualified updates for endorsement and CMS adoption.
- **CMS:** Consider the use of statutory and contractual authority to ensure new evidence and technologies are reflected in the measures CMS uses in its payment and public reporting programs, including potentially selecting alternate measures for use when measures are not updated in a timely fashion. This is particularly relevant to measures developed under CMS contract, recognizing any updated measures will have to be adopted by CMS through rulemaking.
- **USPSTF**: Adhere to statutory five-year review intervals for recommendations currently in the USPSTF library, utilize the early topic update when appropriate (Section 2.6 of the USPSTF Procedure Manual), and ensure those reviews include consideration of new technologies, evaluating if they may improve the accuracy of testing and the willingness of patients to undergo testing. Publish clear schedules and evidence queues to enable measure alignment.
- **The Department of Health and Human Services (HHS):** Assess the need for regulatory guidance establishing expectations for timeliness and evidence use across quality programs to promote consistent, rapid integration of validated screening tests.
- **Congress:** Evaluate the resources needed to enable timely USPSTF reviews and exercise oversight of the existing statutory requirements ("at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess health effects of interventions"). Encourage CMS to enforce timeliness and evidence standards in measure contracts.

Regulatory Authorities: Roles and Impact

Understanding the distinct authorities overseeing screening quality measures is essential for interpreting the implementation pathways established by the ASMM Framework. Each stakeholder possesses unique abilities to shape, update, and enforce the standards upon which national measure sets, like HEDIS, are built.

The following table summarizes the formal authorities, primary impacts of key governance bodies, and their recommended actions in the screening measure ecosystem:

Authority	Formal Role & Authority	Impact on Screening Measures	Recommended Actions
Device Manufacturers	Develop and market technologies for screening and disease detection to improve patient health outcomes.	Create products that are potentially included in measures of appropriate screening.	Submit requests to measure developers and stewards for updates to screening measures when new technologies meet evidentiary thresholds.
Measure Developers and Stewards	Measure developers: Create and test the technical specifications for quality measures. Measure stewards: Own the measures and manage their updates and maintenance over time.	Establish, update, and operationalize measures using input from stakeholders and regulatory partners such as CMS.	Update quality measures at a frequency that is independent of USPSTF updates; consider all appropriate evidence to determine when measure updates are warranted.
CMS	Defines "reasonable and necessary" for coverage; issues NCDs; sets coding/payment policy (42 U.S.C. §1395y and 42 CFR Part 405).	Determines which screening technologies are covered by Medicare, driving early measure adoption and shaping payer standards.	Work with measure developers and other stakeholders to ensure measures in CMS quality measurement programs reflect up-to-date evidence. Consider retiring measures in CMS quality measurement programs that do not reflect inclusion of new technologies that meet the evidence threshold.

USPSTF	Statutorily charged (42 U.S.C. §299b-4) with evidence review and recommendations for preventive services.	A USPSTF "A" or "B" recommendation is required for many preventive services to receive coverage without cost-sharing under federal law. The timing and content of USPSTF updates strongly influence both the pace of quality measure revision and whether new screening technologies are adopted into rating systems, reimbursement, and value-based care contracts. Delays or gaps in recommendations can slow patient access and uptake of novel screening tests throughout the health system.	Adhere to mandated timelines for evaluating and updating screening recommendations.
HHS	Federal oversight and regulatory setting.	Issues policies that align measure priorities with emerging evidence, public health needs, or equity goals.	Direct USPSTF to increase efficiency and frequency in updating screening recommendations and encourage CMS to hold measure developers and stewards accountable for having measures that are consistent with the available evidence.
Congress	Legislative mandates and direction for all agencies.	Can provide sufficient resources for USPSTF and the federal agencies and require more frequent review to expedite measure adoption and modernization.	Delegate increased resources to USPSTF to support timely updates to screening recommendations. If needed, designate specific authorities to CMS or HHS to enhance oversight of timely measure updates.

Device Manufacturers

Device manufacturers are a crucial stakeholder in the screening and preventive services sector, and their work is tightly linked to and impacted by how quality measures are defined and updated across programs. Because of these interdependencies, decisions made by measure stewards and developers have a direct impact on whether and how new technologies are adopted. NCQA is a prominent measure steward that maintains a formal process to keep the HEDIS measures current, adaptable, and aligned with the latest scientific and clinical evidence. However, stakeholders and the ASMM have raised concerns that updates do not always occur as quickly or as transparently as emerging evidence and technologies might warrant. For measures in other programs, similar concerns exist. Under the ASMM Framework, device manufacturers can proactively assess whether their technology meets the evidentiary threshold to support a request to update a relevant screening quality measure. When the evidence is sufficient, manufacturers can submit a structured proposal to the appropriate measure developer asking that the technology be considered as an acceptable screening option, potentially accelerating the integration of new, evidence-supported technologies into clinical practice. The framework operates independent of payer decisions about whether a service is covered with or without cost sharing; its focus is on the evidentiary basis for inclusion in quality measurement.

To develop an effective update request, device manufacturers must provide robust supporting documentation that can demonstrate clinical relevance, patient benefit, and alignment with recognized standards of care.

Measure Developers and Stewards

Measure developers have a critical role in ensuring their measures are consistent with the best available evidence about which screening tests or technologies should be utilized in which populations to deliver accurate results. While the USPSTF reviews evidence about the efficacy and effectiveness of screening for various diseases or disorders and what tests should be used for screenings, the ASMM believes that measure developers and stewards should ensure their own processes to identify when a measure should be updated are robust and current. Measure stewards should use the ASMM Framework for identifying potential triggers prompting a proactive review and update of measures whenever robust new evidence emerges, not just on a fixed calendar. They should accept manufacturer and stakeholder requests for screening measure updates year-round rather than limiting requests to narrow comment windows. All measure developers and stewards should adopt clear, consistent processes for public request and comment so that proposed updates are transparent, timely, and responsive to innovation.

Submission of measure update materials that meet applicable evidentiary standards should initiate a formal reconsideration of an existing measure within six months under the developer's standard review process. Updated measures that meet methodological standards should then be advanced promptly for consensus-based entity endorsement and CMS rulemaking to hasten their use in federal quality and value-based payment programs.

The Federal Government

Federal agencies can choose to influence the implementation of the ASMM Framework through regulatory, contractual, and financial mechanisms. CMS has a responsibility to ensure its quality measures are up to date. This should include appropriate FDA-approved and CMS-covered technologies to avoid penalizing plans or providers for use of evidence-based screening tests and to ensure there are no barriers for patients to access screening options. CMS can establish national standards and priorities, as well as create incentives or program requirements that encourage measure stewards to update or harmonize their measures. For example, CMS could exclude measures in federal programs that are not updated in a timely fashion. Although such expectations are not legally binding, their connection to funding, program eligibility, or public reporting gives agencies considerable leverage to promote timely updates.

Public policy initiatives may further encourage changes, particularly when federal incentives or regulations are aligned with new clinical evidence or accessibility goals. In the absence of direct statutory mandates, the agencies may choose to further engage through formal rulemaking to influence measure updates.

Congress can play a pivotal role by directing HHS to streamline the USPSTF process and increase its resources so statutory five-year review expectations can be met. Congress could also clarify statutory language and direct the HHS Secretary to require that quality measures be reviewed and, when appropriate, updated within defined timelines. In addition, Congress could instruct CMS to use only measures that are updated in a timely manner to include innovative technologies and to incorporate these expectations into contracts with measure stewards.

Conclusion

Effective implementation of this framework depends on coordinated engagement throughout the entire screening ecosystem. Measure developers and stewards, regulators, and manufacturers each hold distinct responsibilities in applying the framework's principles to evaluate emerging evidence, update quality measures, and align operational and policy incentives. Through sustained collaboration and transparent processes, these stakeholders can help ensure that safe, evidence-based screening technologies that meet the standard of care are integrated into clinical practice more efficiently, ultimately improving access and outcomes for patients.