Pew

September 9, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1807–P
P.O. Box 8016
Baltimore, MD 21244–8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

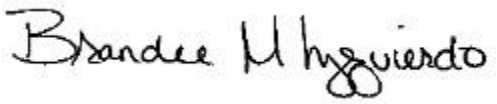
Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services' (CMS) CY 2025 proposed regulations to update health care provider payment policies and reporting programs. We appreciate the agency's leadership in advancing public policies affecting the nation's health, and we are pleased to offer recommendations and feedback relevant to our work on behavioral health and public health topics.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care. Through its Substance Use Prevention and Treatment Initiative (SUPTI), Pew works with states and at the federal level to address the nation's overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for substance use disorders. Pew's Suicide Risk Reduction (SRR) project aims to make suicide risk assessment and care a part of routine health care in the U.S. and to fill gaps between people at risk of suicide and the care they need by empowering hospitals and health systems to expand the use of evidence-based screening and interventions. Pew's Public Health Data

Improvement (PHDI) project conducts research, provides technical assistance, and advocates for policies, resources, and public health department practices to enable the rapid and effective use of health care data to advance Americans' well-being.

Thank you again for the opportunity to provide input and for your continued dedication to these issues. Please contact Kyle Kinner (kkinner@pewtrusts.org) in our Government Relations practice for additional information or questions.

Sincerely,



Brandee Izquierdo, DPA, MPA
Director, Behavioral Health Programs
The Pew Charitable Trusts

Kathy Talkington, MPP
Director, Health Programs
The Pew Charitable Trusts

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Substance Use Prevention and Treatment Initiative (SUPTI)

Through SUPTI, Pew works with states and at the federal level to address the nation's overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for substance use disorders. We are submitting comments to commend the Centers for Medicare and Medicaid Services' (CMS) proposals to make permanent and expand certain telehealth services and support screening and counseling for alcohol and other drug use. We are also writing to provide recommendations to further support access to substance use treatment and medications for opioid use disorder (MOUD).

Buprenorphine and methadone, two of the FDA-approved MOUD, are highly effective and have been proven to reduce overdose deaths, illicit drug use, and disease transmission through injected drugs.[1] Access to this lifesaving treatment however, remains a challenge.[2] Telehealth prescribing of buprenorphine significantly changed the access landscape by reducing barriers to treatment for people living in rural areas, racial and ethnic minorities, people experiencing homelessness, veterans, and people with criminal legal system involvement, with audio-only helping to further address access challenges.[3]

In addition to the access challenges that exist for the treatment opioid use disorder, there are also access challenges for the treatment of other substance use disorders. Long-term alcohol use can contribute to heart disease and other chronic conditions, yet only 12% of people with an alcohol use disorder (AUD) were counseled by their doctor to reduce their alcohol use, a simple intervention that is proven to decrease alcohol use among people who drink heavily or have milder forms of AUD.[4]

Making permanent and expanding certain telehealth services and supporting screening and counseling for alcohol and other drug use are major contributions to expanding access to treatment for substance use disorders. We strongly support the changes to the Physician Fee Schedule discussed below and offer recommendations to further support access to substance use treatment and MOUD.

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Telehealth

Feedback regarding expiration of other telehealth flexibilities – page 101

Pew supports making permanent the critical telehealth flexibilities that improve access and remove barriers to treatment for opioid use disorder (OUD).[5] While telehealth flexibilities related to mental health and substance use disorders are not expiring, CMS data indicates that Medicare beneficiaries with OUD that use telehealth have complex health needs, multiple comorbid conditions, and physical and mental health comorbidities.[6] Maintaining telehealth services beyond those for mental health and substance use disorders may be necessary to meet broader patient needs and support recovery.

Recommendation:

As other telehealth flexibilities are set to expire on December 31,2024, Pew asks CMS to extend flexibilities where appropriate to maintain continuity of care and access to valuable services for patients with OUD.

Permanent inclusion of audio-only in definition of "interactive telecommunications system" - § 410.78(a)(3), page 1686

Pew strongly supports CMS's proposal to permanently include two-way, real-time audio-only communication for any telehealth service in the definition of "interactive telecommunications system" in § 410.78(a)(3), but recommends further revising the definition to allow audio-only services to be provided by physicians or practitioners without regard to the practitioners' technical audio-visual capabilities if they are located in areas with inadequate broadband or other access challenges.[7] Audio-only telehealth helps patients overcome major barriers to buprenorphine treatment including limited transportation, reduced mobility, caregiving responsibilities, inadequate access to technology, and challenges with audio-video technology.[8] Audio-only telehealth buprenorphine treatment is as safe, effective, and high-quality as audio-video telehealth and patients using audio-only for buprenorphine treatment are not more likely to divert their prescriptions.[9]

Requiring physicians or practitioners to be technically capable of using two-way, real-time audio and video equipment places unnecessary barriers on providers in remote parts of the country with limited access to broadband. Video telehealth is not widely available to the 14.5 million people living in the U.S. with inadequate

broadband and challenges with digital literacy, and rural communities may lose access to the benefits of telehealth because they do not have the necessary broadband connection for audio-video telehealth.[10] The Substance Abuse and Mental Health Services Administration (SAMHSA) recognizes the role of telehealth in making mental health and substance use treatment services more accessible and reducing gaps and disparities and has reinforced that "clinicians also need reliable and affordable internet access to provide telehealth services."[11]

Recommendation:
To allow physicians or practitioners that are located in parts of the country with limited access to broadband or other access challenges to offer services via audio-only means, CMS should revise the regulations in § 410.78(a)(3) defining an interactive telecommunications system to allow audio-only services to be provided by physicians or practitioners without regard to the practitioners' technical audio-visual capabilities if they are located in areas with inadequate broadband or face other access or technical challenges. CMS should consult with physicians and practitioners that provide telehealth services on the potential challenges they may experience by being required to be technically capable of using audio-video telehealth to provide audio-only services. Alternatively, CMS could use the CY 2026 PFS proposed rule to seek comment on this requirement and its potential associated challenges.

Opioid Treatment Programs (OTPs)
Feedback regarding the OTP bundle – page 624
As noted below, Pew supports CMS's proposals to align payment for telehealth services in OTPs with SAMHSA's recent revisions to 42 CFR Part 8. Pew also recommends that CMS explore opportunities to revise the base OTP bundle for next year's physician fee schedule.

Currently, OTPs can only bill for services in weeks in which at least one service is provided – either medication or a non-drug service such as counseling.[12] While Pew acknowledges that CMS has a duty to manage costs within the Medicare program, it is possible that the current payment approach will incentivize providers to limit take-home doses to a one-week supply or require clients to participate in counseling regardless of whether such a service is needed or desired. This outcome appears contrary to the intent of SAMHSA's updated regulations,

which allow clients to quickly become eligible for 14-28 days of take-home doses and emphasize that medication should not be contingent on counseling.[13]

Pew concurs with the recommendation of the *Liberating Methadone* conference report, a roadmap for patient-centered methadone treatment grounded in living and lived expertise of methadone treatment, that "the Medicare bundled payment structure should be updated to incentivize best practices in care."[14]

Recommendation:
To make these changes, CMS should consider convening patients, providers and other stakeholders to obtain their input on a payment model which would incentivize patient-centered care while also managing costs within the Medicare program.

Permanently allow audio-only periodic assessments furnished by Opioid Treatment Programs - § 410.67(b)(vii), page 1686
Pew commends CMS's proposal to make permanent the audio-only flexibilities for periodic assessments furnished by OTPs beginning January 1, 2025. Audio-only telehealth is valuable for individuals who are older, Black, Hispanic, American Indian/Alaskan Native, Spanish-speaking, living in areas with low broadband access, low-income, and with public insurance.[15] Making permanent the audio-only flexibilities for periodic assessments provided by OTPs reinforces CMS's ongoing commitment to Medicare patients' health equity interests and will help to address or mitigate disparities in OUD treatment.

Allow initiation of methadone treatment via audio-video telehealth furnished by OTPs - § 410.67(b)(vi)(A)(2), page 1686
Pew supports CMS's proposal to allow initiation of methadone treatment through audio-video telehealth provided by an OTP. As noted in Pew's comment letter for SAMHSA's proposed changes to OTP regulations at 42 CFR part 8, providing MOUD via telehealth increases treatment access for underserved groups and helps patients start and stay in treatment, with audio-only telehealth playing a major role in addressing health disparities.[16]

Recommendation:
Pew strongly supports CMS's proposal to allow initiation of methadone treatment through audio-video telehealth and asks the agency to evaluate the evidence on audio-only initiation of methadone and consider flexibilities that would maximize access to all types of MOUD, improve access parity for buprenorphine and methadone, reduce stigma around methadone, and promote practitioner autonomy.[17] Pew acknowledges the lack of research on audio-only provision of methadone, and asks the agency to partner with the National Academies of Sciences, Engineering, and Medicine to assess the evidence base and appropriateness of audio-only initiation of methadone and propose policy changes in line with the evidence. In the interim, if appropriate, the agency may wish to consider the use of waivers for individual cases in which audio-only evaluation is the only way the patient can access services and the lack of availability of a licensed practitioner registered to prescribe and dispense controlled medications in the patient's presence creates a barrier to access.

Screening for alcohol and other drug use
Valuation of alcohol screening and counseling – page 181
Pew supports CMS's proposal to pay for and appropriately value alcohol screening and counseling through changes to *Annual alcohol misuse screening, 5 to 15 minutes* and *Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*. Screening and counseling for alcohol use create opportunities for behavior change and access to treatment.[18] From 2015 to 2021, just 12% of people with an alcohol use disorder (AUD) were counseled by their doctor to reduce their alcohol consumption, a simple intervention that is proven to reduce alcohol consumption among people who drink heavily or have milder forms of AUD.[19] It is estimated that less than 10% of people who need AUD treatment receive it, and that only 2% access FDA-approved medications for AUD.[20]

Recommendation:
To continue to monitor research on alcohol screening, counseling, and treatment and incorporate research findings into the valuation and payment of these services.

Inclusion of screening for alcohol and other drug use in cardiovascular risk assessment – page 332

Pew supports CMS's inclusion of screening for alcohol and other drug use in its proposal for coding and payment for an Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service and risk management services.

While research on the impact of screening for alcohol and other drug use in specialty care is limited, such screening in primary care settings creates opportunities for behavior change and improved access to treatment.[21] Nearly 90,000 alcohol-related deaths each year can be attributed to chronic conditions related to prolonged alcohol use, including heart disease.[22] Chronic stimulant use is also known to cause damage to the cardiovascular system.[23]

Recommendation:

To continue to monitor research on screening for alcohol and other drug use and incorporate research findings into the valuation and payment of these services and incorporate these screenings into other appropriate services.

Suicide Risk Reduction (SRR)

Through SRR, Pew seeks to fill the gaps between people at risk of suicide and the care they need by empowering health care providers to expand the use of evidence-based practices and interventions. Our goal is to help make suicide risk assessment and care part of routine health care in the U.S. We write today to applaud the Centers for Medicare and Medicaid Services' (CMS) proposal to establish billing codes for the creation of safety planning intervention (SPI) and follow-up contacts intervention (FCI) for patients in crisis, including those at risk for suicide, and express support for implementing these codes in CY 2025.

Research indicates that for people admitted to the hospital for suicidal thoughts or behaviors, the period following discharge is a time of increased risk for suicide.[24] SPI and FCI are two interventions used in emergency departments (EDs), or similar health care settings, that have shown to be effective at reducing subsequent suicide attempts or death among people with suicide risk.[25] These complementary interventions are found to be most effective when they are implemented together.[26] However, a nationally representative survey found that SPI and FCI are underutilized.[27] About 60% of accredited hospitals surveyed in the study reported some form of safety planning activities, yet only 19% of these hospitals reported implementing all elements of SPI in a manner that is consistent with what experts consider best practice.[28] Further, only 30% reported that they conduct FCI after discharge.[29] Challenges to increase utilization of these suicide care practices include increased burden on providers, as reported by 42% of hospitals, and logistical concerns about tracking discharged patients to receive interventions on schedule, as reported by 35% of hospitals.[30]

The development of designated billing codes for SPI and FCI will incentivize hospitals to provide these services and help expand implementation of these interventions for individuals with suicide risk. It will also establish a valid and reliable way to determine if and track when a patient receives SPI and FCI, which can help improve fidelity and data collection for quality improvement purposes. We strongly support the development of SPI and FCI billing codes and offer the following recommendations to enable these interventions to be implemented more feasibly.

SPI should be billed as a standalone service rather than the current proposal of SPI as an add-on to evaluation/management (E/M) or psychotherapy visits – page 371

Due to its proven effectiveness at reducing subsequent suicide attempts for people with suicide risk, SPI should be furnished when indicated, regardless of whether the visit is in context of an E/M or psychotherapy encounter.[31] E/M and psychotherapy visits are typically furnished by licensed practitioners who are permitted to bill Medicare, but SPI can be offered by a wide range of trained health care providers.[32] Requiring SPI to be an add-on service can create unnecessary logistical and financial barriers for licensed practitioners and other providers. Further, psychotherapy and behavioral health services are not always available to many patients experiencing suicide risk due to systemic barriers, including stigma, availability of providers, especially culturally and linguistically competent providers, and cost.[33]

SPI should be furnished by a licensed practitioner and other appropriate staff under the supervision of a licensed practitioner – page 371

The proposal requires SPI to be furnished by the same practitioner who conducts the E/M or psychotherapy visit, which is typically a licensed practitioner who can bill Medicare. Research supports that clinicians with a wide range of backgrounds can be trained to effectively and safely administer SPI, including appropriate members of the hospital's clinical staff, such as nurses.[34] Restricting this service to licensed practitioners creates logistical barriers for SPI to be furnished when indicated. Increasing the number of providers who are available to provide this service will improve accessibility and availability of SPI for patients at risk for suicide.

SPI encounters should be more than 20 minutes – page 371

The proposed rule assumes a typical time of 20 minutes for SPI. Research indicates that SPI takes about 30-45 minutes, based on case complexity.[35] Twenty minutes should be the minimum needed to furnish SPI.

FCI should be furnished by month for at least three months after relevant index events, providing for 60 minutes (4 phone calls) of call-time per month – page 373

The current rule proposes a billing code that allows for four calls in a month, each lasting 10-20 minutes, and seeks comment on the duration FCI can be furnished following discharge. Based on the existing data of research-based and pilot FCI programs that reduced subsequent suicidal behavior, we recommend the duration of time allowing FCI to be furnished to be at least three months. In a study looking at Veterans Health Administration hospitals, the FCI included two brief telephone calls following ED discharge "to assess risk, review and revise the safety plan, and support treatment engagement," and calls continued on a weekly basis until the patient began treatment or withdrew.[36] In the ED-SAFE Study, patients in the intervention phase received up to seven calls for 52 weeks.[37] In a pilot program in Colorado, discharged ED patients receive a minimum of five follow up calls.[38] Other studies on FCI that resulted in reduced suicidal behavior included regular follow-up contact for three to 18 months.[39]

Public Health Data Improvement (PHDI)

State and local public health officials need timely, comprehensive health data from hospitals, doctors' offices, and clinical labs to detect and respond to disease hot spots, contaminated food and water, and populations experiencing inequitable health outcomes, such as higher rates of environmentally triggered conditions like asthma. PHDI's work is focused on supporting timely, interoperable health data exchange to ensure that public health officials have the information they need to make well-informed decisions that support community health.

Request for Information (RFI) Regarding Public Health Reporting and Data Exchange – page 1351

Pew offers responses and recommendations to the RFI regarding public health reporting and data exchange. More precise measurement, through the use of numerator/denominator reporting in the Medicare Promoting Interoperability performance category, is essential in helping public health agencies to better understand how to protect their communities and allocate resources appropriately.

Responses to Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

Pew applauds CMS' ongoing efforts to improve data exchange between Merit-based Incentive Payment System (MIPS) eligible clinicians and public health agencies through the Promoting Interoperability performance category. Clinicians provide essential data that public health agencies need to detect, prevent, and respond to infectious diseases, environmental hazards, and other threats. Requirements incorporated in earlier years of the program have led to notable increases in the percentage of clinicians sending data to public health agencies. For example, when immunization registry reporting was required in Stage 2 of the Meaningful Use Program, reporting on this measure increased by more than 40% from 2011 to 2014.[40] Although there have been notable increases in the share of clinicians reporting data to public health agencies, major gaps remain in the quality, timeliness, and completeness of this data.

CMS plays a vital role in supporting public health data exchange. Unfortunately, the current approach of active engagement reporting does not allow CMS to assess the level of performance that MIPS eligible clinicians have achieved in sending this data to public health agencies. **Pew encourages CMS to shift from attestation-based measures to ones that move clinicians towards actively demonstrating the quality, timeliness, and completeness of the data they are reporting to public health agencies.** Performance measures are essential to ensuring that clinicians are sending high-quality, real-time information that public health agencies can use to prevent illness and promote wellness in the jurisdictions they serve.

Pew worked directly with an external research organization from 2021-2022 to identify potential performance-based public health measures. The researchers conducted a literature review to characterize existing public health reporting processes and interviewed 34 subject matter experts in late 2021 to determine potential metrics, approaches to quality measures, and barriers to collecting timely, complete, and high-quality data. Next, the research team conducted tests within electronic health record (EHR) systems to better understand the feasibility of data extraction from EHRs for public health use cases. Finally, in March 2022, researchers convened expert panels to generate proposed measures and obtain input and agreement on them; experts included EHR vendors, health information exchange representatives, public health agency leaders, public health organizations, front-line clinical providers, informatics specialists, public health and clinical researchers, and public health law and policy leaders.

Based on our research, Pew proposes that CMS phase in the following measure for numerator/denominator reporting in the Medicare Promoting Interoperability performance category:

Immunization registry reporting: Successful electronic submission for a minimum of 90% of all vaccines administered within 24 hours out of total administered.

Using a phased approach, CMS may require numerator/denominator reporting on the measure but delay specific performance requirements in the first year. This would allow the agency to gather information on the baseline level of performance for clinicians, while also providing valuable data to inform and

further calibrate the appropriate performance metric in the final implementation phase. This approach could be used for the proposed immunization registry reporting measure and allows CMS to adjust if needed to accommodate lesser resourced clinicians who may require a longer phase-in period.

The expert panel recommended successful electronic submission occur within 24 hours to align with CDC's Immunization Information Systems Data Quality Blueprint, which defines timely immunization data as being recorded within one day.[41] The Association of Immunization Registries (AIRA) recommends the development and use of timeliness targets for exchange between certified health information technology (IT) and immunization information system (IIS) registries to support various data needs, including during an outbreak when timely data can help public health agencies assess the vulnerability of the populations they serve.[42] As EHR interfaces are becoming increasingly capable of sharing data in real time, it is reasonable to expect that this transaction occurs within 24 hours.

In Spring 2024, Pew sought feedback on its proposed measure from the National Association of Community Health Centers (NACHC), the leading national advocacy organization in support of community health centers and the expansion of health care access for the medically underserved and uninsured and the American Immunization Registry Association (AIRA), a membership organization that promotes the development and implementation of immunization information systems as a tool for preventing and controlling vaccine-preventable diseases. NACHC and AIRA are supportive of Pew's proposed measure for immunization registry reporting. AIRA agrees that the measure is reasonable and realistic to meet. Pew strongly recommends that CMS adopt the proposed measure in context of the additional provisions discussed below.

Pew recommends that CMS prioritize the immunization registry reporting measure for numerator/denominator reporting. CMS plays an important role in promoting timelier and more complete immunization data that would improve public health agencies' analytic capabilities to better target vaccine resources and support public health efforts. Requiring numerator/denominator reporting for the immunization measure would align CMS with ONC's final HTI-1 rule that introduced an "Insights Condition" measure that will allow ONC to calculate the percent of immunization administrations that are electronically submitted to an IIS

through certified health information technology (IT) by requiring certified health IT developers to submit these metrics.[43] While ONC can measure immunization registry reporting, CMS should incentivize clinicians to meet an attainable but robust reporting threshold in the interest of public health. Although ONC's Insights Condition for immunization reporting does not yet include a timeliness component (e.g., within 24 hours), ONC stated that it may consider adding such a metric in the future.[44]

Pew further recommends that CMS align its timeline for implementing the proposed immunization registry reporting measure with ONC's timeline for phasing in the Insights Condition immunization measure requirement for certified EHR technology. ONC will require certified heath IT developers to submit the number of immunizations administered overall and the number of immunizations administered that are successfully electronically submitted to IISs overall in Year 1, which starts in calendar year 2026.[45] Responses are due in July 2027, and annually thereafter.[46] Aligning timelines with ONC could reduce the burden of reporting this revised immunization measure for MIPS eligible clinicians. However, if implementation of the Insights Condition measure for immunization is delayed, Pew recommends that CMS move forward with implementing Pew's proposed immunization measure.

Pew is supportive of a bonus, attestation-based measure on the use of Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) to support electronic case reporting (eCR) to public health agencies. FHIR promises to be a critical tool for improving data sharing between clinicians and public health agencies. Groups like the Helios FHIR Accelerator for Public Health, which aims to ensure public health data needs are considered as the FHIR standard evolves, are currently exploring ways to improve interoperability while also aligning with public health priorities.[47] Recognizing progress in the use of FHIR for public health, ONC now requires that certified EHR technology support eCR using either Health Level 7 (HL7) Clinical Data Architecture (CDA) or FHIR standards.[48] In its HTI-2 proposed rule, ONC suggests that Health IT Modules be required to use the HL7 FHIR eCR Implementation Guide only, thereby expiring the CDA-based standard, on January 1, 2028.[49] Some EHR vendors are already using the eCR Now FHIR App, which automates the electronic reporting of cases of COVID-19 and can

be configured to support full eCR, to send electronic case reports in a FHIR format, and many others are in the process of adopting its use.[50]

ONC further recommends in the HTI-2 proposed rule that health IT for public health must receive electronic case reporting information via FHIR APIs. Although progress has been made in the use of FHIR for public health, many public health agencies can only accept HL7 CDA documents. Without more time or resources made available to public health agencies to ensure that their IT systems can receive electronic case reports according to the FHIR standard, it would be premature for CMS to require such reporting. Pew recommends that an attestation-based measure assessing the use of FHIR for eCR be introduced as a bonus measure, rather than a required one. Such a measure would better align with ONC's existing regulatory flexibility that allows certified EHR technology to create an electronic case report based on either the CDA or FHIR standard, and proposed regulations that do not set a date by which health IT for public health must conform to the FHIR standard.

The electronic reporting of notifiable health conditions can improve the flow of timely, standardized, and complete information to public health agencies about what diseases and conditions are prevalent in their communities. However, much more progress is needed to increase adoption of eCR. Of the 18% of primary care physicians who acknowledged electronically exchanging information with public health agencies, just 45% of those use eCR to report data.[51] And according to Pew research conducted between May and August 2021, there were no states that use eCR for all reportable conditions.[52] Recent improvements, spurred by advances in eCR for COVID-19, have been made in public health's ability to receive data for other conditions.[53] CMS can play a role in incentivizing eCR and supporting federal efforts to increase adoption but because notifiable conditions vary by jurisdiction, it would be challenging for CMS to set a single national benchmark for eCR at this time. Pew recommends that CMS explore one of two options to remedy this challenge: **1) CMS could incentivize an eCR measure that accounts for various jurisdictional requirements for mandatory reportable conditions; or 2) CMS—in close collaboration with the CDC, state and local public health partners, and other stakeholders—could determine which conditions are most critical to electronically report to public health agencies, then incentivize reporting of those conditions.** Determination of those conditions could set a national floor and

CMS could incentivize the electronic reporting of those conditions for public health surveillance, potentially improving eCR for more conditions. Such a measure should include exclusions or phase-ins to account for public health agency readiness to ingest data for these conditions.

As CMS considers additional levers within the MIPS Promoting Interoperability performance category for improving the completeness of reporting to public health agencies, Pew has identified an additional opportunity that warrants CMS' consideration. **Pew urges CMS to require the submission of the syndromic surveillance reporting measure in MIPS.** Outpatient physicians working outside of emergency departments, such as those who practice at urgent care facilities, generate meaningful syndromic surveillance data that would substantially benefit public health agencies' ongoing disease surveillance. As more and more patients are visiting urgent care clinics instead of emergency departments, public health agencies may be missing critical data to detect and respond quickly to emerging threats. Officials in many states find that the Medicare Promoting Interoperability Program effectively incentivizes hospitals to report syndromic surveillance data.[54] Requiring the syndromic surveillance reporting measure under MIPS could similarly incentivize eligible clinicians to report this data. Moreover, a requirement to report syndromic data in MIPS would better align with the reporting requirement in the Medicare Promoting Interoperability Program and would enable public health agencies to expand the data sources they receive. Given the significance to current and future public health efforts, CMS should require syndromic surveillance reporting in future payment policies under MIPS.

Responses to Questions for Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise

In 2015, just less than half of eligible professionals participating in Stage 2 of Meaningful Use either claimed an exemption or did not report on immunization registry reporting.[55] Moreover, a 2023 U.S. Government Accountability Office report found that small and rural providers were more likely to exchange patient information via mail or fax rather than electronic methods due to limited financial and/or technological resources.[56] To potentially remedy these challenges, **Pew recommends that CMS, in close collaboration with ONC, explore offering a payment adjustment for lower-resourced clinicians to update their health IT**

systems to meet new data needs. It is critical that lower-resourced clinicians are not left behind in data modernization efforts. ONC could provide ongoing guidance to CMS on the requirements for certified EHR technology to ensure that provider systems continue to meet minimum data standards.

Responses to Questions for Goal #3: Increasing Bi-Directional Exchange with Public Health Agencies

Pew supports the introduction of a measure to allow clinicians to receive credit for the Health Information Exchange (HIE) objective by exchanging public health data through participation in the Trusted Exchange Framework and Common Agreement (TEFCA). Through its Public Health Infrastructure Grant, CDC has funded the Association of State and Territorial Health Officials, the Network of Public Health Institutes, and the Public Health Accreditation Board to select three Implementation Centers to support public health agencies in accelerating public health agency data modernization activities, including conducting TEFCA-based data exchange. This effort aligns with CDC's Public Health Data Strategy, in which CDC aims to launch at least two public health use cases for TEFCA in 2024, and two additional ones in 2025.[57] Furthermore, proposed requirements for health IT for public health would allow such technology to optionally demonstrate receipt of public health data through a TEFCA connection.[58] While CDC provides technical assistance and other support to public health agencies to conduct TEFCA-based data exchange, CMS can incentivize eligible clinicians to exchange public health data via TEFCA. Stakeholders have acknowledged the potential benefits of TEFCA for public health in fostering interjurisdictional data exchange, reducing costs associated with connecting to multiple, different networks, and improving availability of quality data.[59] Incentivizing the exchange of public health data through participation in TEFCA will help CDC increase clinician reporting and strengthen bi-directional exchange with public health agencies.

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Responses to Questions for Goal #4: Eliminating Reporting Burden for Healthcare Providers

As CMS continues to consider performance-based public health measures, Pew encourages the agency to work closely with ONC to align any revised measures with future iterations of ONC's Insights Condition measures to reduce reporting burden for clinicians. ONC has expressed an interest in introducing new Insights Condition measures, such as for eCR and syndromic surveillance.[60] As Health IT vendors build the capability to capture this data into their EHR and other reporting systems, CMS can incentivize performance in its payment policies by setting defined targets. Coordination across the two agencies would promote further consistency across programs and potentially reduce the burden on clinicians.

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[1] The Pew Charitable Trusts, "State Policies Can Expand Access to Buprenorphine for Opioid Use Disorder," The Pew Charitable Trusts, 2023, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2023/11/state-policies-can-expand-access-to-buprenorphine-for-opioid-use-disorder.
[2] The Pew Charitable Trusts, "State Policies Can Expand Access to Buprenorphine for Opioid Use Disorder."
[3] Marcelo H. Fernández-Viña and Sheri Doyle, "Congress Should Permanently Extend Telehealth Flexibilities," accessed February 9, 2024, January 29, 2024, https://www.pewtrusts.org/en/research-and-analysis/articles/2024/01/29/congress-should-permanently-extend-telehealth-flexibilities.
[4] The Pew Charitable Trusts, "Americans Face More Than an Opioid Overdose Crisis," May 17, 2024, https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2024/americans-face-more-than-an-opioid-overdose-crisis.
[5] Marcelo H. Fernández-Viña and Sheri Doyle, "Congress Should Permanently Extend Telehealth Flexibilities."
[6] Centers for Medicare & Medicaid Services, "Changes in Access to Medication Treatment During Covid-19 Telehealth Expansion and Disparities in Telehealth Use for Medicare Beneficiaries with Opioid Use Disorder," January 2022, https://www.cms.gov/files/document/data-highlight-jan-2022.pdf.
[7] The Pew Charitable Trusts, "Re: Medicare and Medicaid Programs; Cy 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (Cms 1784-P)," https://www.pewtrusts.org/-/media/assets/2023/03/pew-comments-dea-rin-1117ab78-v3final.pdf.
[8] Marcelo H. Fernández-Viña and Sheri Doyle, "Congress Should Permanently Extend Telehealth Flexibilities."
[9] Brandee Izquierdo and Sheri Doyle, "With a Boost from Congress, Telehealth Can Help Stop Overdose Deaths," January 11, 2024, https://www.pewtrusts.org/en/about/news-room/opinion/2024/01/11/with-a-boost-from-congress-telehealth-can-help-stop-overdose-deaths.
[10] The Pew Charitable Trusts, "Re: Medicare and Medicaid Programs; Cy 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (Cms 1784-P)."

[11] Yosselin Turcios, "Digital Access: A Super Determinant of Health," 2023, https://www.samhsa.gov/blog/digital-access-super-determinant-health.
[12] Centers for Medicare & Medicaid Services, "Opioid Treatment Programs (Otp) - Billing & Payment - Spotlight - Otp G-Codes for Intake Activities," 03/11/2024, https://www.cms.gov/medicare/payment/opioid-treatment-program/billing-payment.
[13] Department of Health and Human Services, Medications for the Treatment of Opioid Use Disorder, 42 Cfr Part 8, Rin 0930-Aa39, (2024), https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder.
[14] National Coalition to Liberate Methadone, National Survivors Union, and NYU Langone Center for Opioid Epidemiology and Policy (COEP), "Liberating Methadone: A Roadmap for Change - Conference Proceedings and Recommendations," 2024, https://drive.google.com/file/d/1eRwpgfpfuR9Miphk5b7BsHRs4TEeYOBC/view.
[15] The Pew Charitable Trusts, "Re: Medicare and Medicaid Programs; Cy 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (Cms 1784-P)."
[16] The Pew Charitable Trusts, "Re: Rin 0930-Aa39, Notice of Proposed Rulemaking, 42 Cfr Part 8," https://www.pewtrusts.org/-/media/assets/2023/02/pew-comments-rin-0930-aa39.pdf.
[17] The Pew Charitable Trusts, "Re: Rin 0930-Aa39, Notice of Proposed Rulemaking, 42 Cfr Part 8."
[18] Felicia W. Chi et al., "Alcohol Brief Intervention, Specialty Treatment and Drinking Outcomes at 12 Months: Results from a Systematic Alcohol Screening and Brief Intervention Initiative in Adult Primary Care," *Drug and Alcohol Dependence* 235 (2022): 109458, https://www.sciencedirect.com/science/article/pii/S0376871622001958.; Ethan Sahker et al., "Screening, Brief Intervention, and Referral to Treatment Demonstrates Effectiveness in Reducing Drinking in a Midwest American Service Sample," *International Journal of Mental Health and Addiction* 18, no. 1 (2020): 138-48, https://link.springer.com/article/10.1007/s11469-018-9953-1.
[19] The Pew Charitable Trusts, "Americans Face More Than an Opioid Overdose Crisis."
[20] The Pew Charitable Trusts, "Millions of Americans Have Alcohol Use Disorder, but Few Get Treatment," June 6, 2024, https://www.pewtrusts.org/en/research-and-analysis/articles/2024/06/06/millions-of-americans-have-alcohol-use-disorder-but-few-get-treatment.
[21] Felicia W. Chi et al., "Alcohol Brief Intervention, Specialty Treatment and Drinking Outcomes at 12 Months: Results from a Systematic Alcohol Screening and Brief Intervention Initiative in Adult Primary Care."; Ethan Sahker et al., "Screening, Brief Intervention, and Referral to Treatment Demonstrates Effectiveness in Reducing Drinking in a Midwest American Service Sample."; U.S. Preventative Health Services Task Force, "Unhealthy Drug Use: Screening - Final Recommendation Statement," 2020, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/drug-use-illicit-screening.
[22] The Pew Charitable Trusts, "Americans Face More Than an Opioid Overdose Crisis."
[23] The Pew Charitable Trusts, "Stimulant Use Is Contributing to Rising Fatal Drug Overdoses," August 12, 2024, https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2024/08/stimulant-use-is-contributing-to-rising-fatal-drug-overdoses.
[24] Sidra Goldman-Mellor et al., "Association of Suicide and Other Mortality with Emergency Department Presentation," *Journal of the American Medical Association* 2, no. 12 (2019): e1919571, 10.1001/jamanetworkopen.2019.17571.
[25] J. John Mann, Christina A. Michel, and Randy P. Auerbach, "Improving Suicide Prevention through Evidenced-Based Strategies: A Systematic Review," *American Journal of Psychiatry* 178, no. 7 (2021): 611-24,

10.1176/appi.ajp.2020.20060864. Barbara Stanley and Gregory K. Brown, "Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk," *Cognitive and Behavioral Practice* 19 (2012): 256-64, https://www.sciencedirect.com/science/article/pii/S1077722911000630#bb0180. Ivan W. Miller et al., "Suicide Prevention in an Emergency Department Population: The Ed-Safe Study," *JAMA Psychiatry* 74, no. 6 (2017): 563-70, http://dx.doi.org/10.1001/jamapsychiatry.2017.0678 . Barbara Stanley et al., "Comparison of the Safety Planning Intervention with Follow-up Vs Usual Care of Suicidal Patients Treated in the Emergency Department," *JAMA Psychiatry* 75, no. 9 (2018): 894-900, 10.1001/jamapsychiatry.2018.1776.

[26] Barbara Stanley et al., "Comparison of the Safety Planning Intervention with Follow-up Vs Usual Care of Suicidal Patients Treated in the Emergency Department."

[27] Salome O. Chitavi et al., "Evaluating the Prevalence of Four Recommended Practices for Suicide Prevention Following Hospital Discharge," *The Joint Commission Journal on Quality and Patient Safety* 50, no. 6 (2024): 393-403, https://doi.org/10.1016/j.jcjq.2024.02.007.

[28] Salome O. Chitavi et al., "Evaluating the Prevalence of Four Recommended Practices for Suicide Prevention Following Hospital Discharge."

[29] Salome O. Chitavi et al., "Evaluating the Prevalence of Four Recommended Practices for Suicide Prevention Following Hospital Discharge."

[30] Salome O. Chitavi et al., "Evaluating the Prevalence of Four Recommended Practices for Suicide Prevention Following Hospital Discharge."

[31] Ivan W. Miller et al., "Suicide Prevention in an Emergency Department Population: The Ed-Safe Study.";

[32] Barbara Stanley and Gregory K. Brown, "Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk."

[33] National Center for Health Workforce Analysis "Behavioral Health Workforce, 2023," Health Resources & Services Administration, 2023, https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Behavioral-Health-Workforce-Brief-2023.pdf.

[34] Barbara Stanley and Gregory K. Brown, "Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk." Barbara Stanley et al., "Comparison of the Safety Planning Intervention with Follow-up Vs Usual Care of Suicidal Patients Treated in the Emergency Department.". Ivan W. Miller et al., "Suicide Prevention in an Emergency Department Population: The Ed-Safe Study."

[35] Christa D. Labouliere et al., "Safety Planning on Crisis Lines: Feasibility, Acceptability, and Perceived Helpfulness of a Brief Intervention to Mitigate Future Suicide Risk," *Suicide and Life-Threatening Behavior* 50, no. 1 (2019): 29-41, 10.1111/sltb.12554.; Barbara Stanley and Gregory K. Brown, "Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk." Barbara Stanley and Gregory K. Brown, "The Safety Planning Intervention to Reduce Suicide Risk for People with Smi" (presentation, TA Coalition Webinar: The Safety Planning Intervention to Reduce Suicide Risk, 2019), https://www.nasmhpd.org/content/ta-coalition-webinar-safety-planning-intervention-reduce-suicide-risk.

[36] Barbara Stanley et al., "Comparison of the Safety Planning Intervention with Follow-up Vs Usual Care of Suicidal Patients Treated in the Emergency Department."

[37] Ivan W. Miller et al., "Suicide Prevention in an Emergency Department Population: The Ed-Safe Study."

[38] Brittany Catanach et al., "Implementing an Emergency Department Telephone Follow-up Program for Suicidal Patients: Successes and Challenges," *The Joint Commission Journal on Quality and Patient Safety* 45, no. 11 (2019): 725-32, https://doi.org/10.1016/j.jcjq.2019.07.009

[39] Gregory K. Brown and Kelly L. Green, "A Review of Evidence-Based Follow-up Care for Suicide Prevention: Where Do We Go from Here?," *American Journal of Preventive Medicine* 47, no. 3S2 (2014): S209-S15, http://dx.doi.org/10.1016/j.amepre.2014.06.006.
[40] Centers for Medicare & Medicaid Services, "Stage 2 Overview Tipsheet," news release, August 2012, https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/stage2overview_tipsheet.pdf.; The Office of the National Coordinator for Health Information Technology, "Electronic Reporting to Immunization Information Services (Iis) among Medicare Eligible Professionals, 2011-2014," accessed February 12, 2021, April 2015, https://dashboard.healthit.gov/quickstats/pages/medicare-eps-immunization-registry-reporting-trend.php.
[41] Centers for Disease Control and Prevention, "Immunization Information Systems Data Quality Blueprint," https://www.cdc.gov/vaccines/programs/iis/downloads/Data-Quality-Blueprint-508.pdf.
[42] American Immunization Registry Association, "Iis Data Quality Practices," https://repository.immregistries.org/files/resources/5c002cbde216d/aira_dq_guide_data_at_rest_-_final.pdf.
[43] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule), (2024), https://www.govinfo.gov/content/pkg/FR-2024-01-09/pdf/2023-28857.pdf.
[44] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).
[45] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).
[46] Office of the National Coordinator for Health Information Technology, "Hti-1 Insights Condition Fact Sheet," https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_Insights_factsheet_508.pdf.
[47] Joshua Procious, "Helios Fhir Accelerator for Public Health Home," https://confluence.hl7.org/display/PH.
[48] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).
[49] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (Proposed Rule), (2024), https://www.govinfo.gov/content/pkg/FR-2024-08-05/pdf/2024-14975.pdf.
[50] Association of Public Health Laboratories, "Ecr Now Fhir App," https://ecr.aimsplatform.org/ecr-now-fhir-app.; A.D. Schmit, 2024, May 15, 2024.
[51] Chelsea Richwine, Dustin Charles, and Vaishali Patel, "Electronic Public Health Reporting & Recording of Social & Behavioral Determinants of Health among Office-Based Physicians, 2019," Office of the National Coordinator for Health Information Technology, 2022, https://www.healthit.gov/data/data-briefs/electronic-public-health-reporting-recording-social-behavioral-determinants-health.
[52] The Pew Charitable Trusts, "Unpublished Data" (working paper).
[53] Council of State and Territorial Epidemiologists, "Dmi Stories from the Field: Electronic Case Reporting," https://stories.cste.org/?page_id=449.
[54] The Pew Charitable Trusts, "Unpublished Data."
[55] The Office of the National Coordinator for Health Information Technology, "Electronic Reporting to Immunization Information Services (Iis) by Stage of Meaningful Use," accessed December 23, 2020,

https://dashboard.healthit.gov/quickstats/pages/medicare-eps-immunization-registry-reporting-stage-one-and-two.php.

[56] United States Government Accountability Office, Electronic Health Information Exchange Use Has Increased, but Is Lower for Small and Rural Providers, GAO-23-105540 (2023), https://www.gao.gov/assets/gao-23-105540.pdf.

[57] Centers for Disease Control and Prevention, "Public Health Data Strategy Milestones for 2024 and 2025," https://www.cdc.gov/ophdst/public-health-data-strategy/phds-milestones.html.

[58] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (Proposed Rule).

[59] Association of Public Health Laboratories, "Comments on the Draft Trusted Exchange Framework and Common Agreement," https://www.aphl.org/programs/informatics/Documents/Comments%20on%20the%20Drafted%20Trusted%20Exchange%20Framework%20and%20Common%20Agreement.pdf.; American Immunization Registry Association, "Public Comment of Draft Trusted Exchange Framework and Us Core Data for Interoperability," https://repository.immregistries.org/files/resources/5a85e9510ecfe/aira_letter_and_comments_-_trusted_exchange_framework_final_new_logo-1.pdf.

[60] Office of the National Coordinator for Health Information Technology, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).