

2005 Market Street, Suite 2800	P 215.575.9050
Philadelphia, PA 19103-7077	F 215.575.4939

901 E Street NW, 10th Floor Washington, DC 20004 pewtrusts.org P 202.552.2000F 202.552.2299

September 6, 2022

Administrator Brooks-LaSure Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1770-P

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure,

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services (CMS)' proposed regulations to update health care provider payment policies and reporting programs. We appreciate your leadership on advancing public policies affecting the nation's health, and we urge CMS to finalize provisions in the proposed rule that are key to: (1) strengthening the Meritbased Incentive Payment System (MIPS) Promoting Interoperability performance category within the Quality Payment Program (QPP) by addressing aspects of electronic health record (EHR) use that aid public health efforts; (2) expanding access to evidence-based treatment for patients with substance use disorder via telehealth; (3) addressing the growing need for opioid use disorder (OUD) treatment among Medicare beneficiaries; and (4) collecting data on these services, through CY2023, which will inform decisions regarding their inclusion as permanent additions to Medicare's telehealth services, to the extent allowed under federal law.

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, Pew works with states, and at the federal level, to address the nation's opioid overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for OUD. In addition, Pew's Public Health Data Improvement 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 to CMS for the opportunity to provide input and for your continued dedication to this issue. Please contact Kyle Kinner (<u>kkinner@pewtrusts.org</u>) in our Government Relations practice for additional information or questions.

Sincerely,

Lach & Jun

Kathy Talkington Director, Health Programs The Pew Charitable Trusts

Comments Related to the Promoting Interoperability Performance Category for MIPS Eligible Clinicians

Pew commends the efforts CMS has taken to enhance data exchange through the Promoting Interoperability performance category under MIPS, which encourages health care providers to use EHRs in meaningful ways. Pew supports CMS in building on its previous actions to strengthen incentives that further drive public health reporting. By continuing to address aspects of EHR use that aid public health efforts, CMS can encourage providers to electronically share timely, granular, and robust data that inform decisions and actions essential for responding to public health threats, reducing health inequities, and improving population health.

As proposed, the following modifications and requirements in the rule, beginning with the calendar year (CY) 2023 performance period, would continue to significantly improve how EHRs help inform public health agencies' activities and strengthen automatic data reporting to authorities:

• Public Health and Clinical Data Exchange Objective

- Pew supports the consolidation of options from three phases to two, in which the level of active engagement for MIPS eligible clinicians must occur in one of the following two phases:
 - 1. <u>Pre-production and validation</u> (i.e., the MIPS eligible clinician has completed registration to submit data *and* is in the process of testing and validating electronic data submission); or
 - 2. <u>Validated data production</u> (i.e., the MIPS eligible clinician has completed testing and validation of electronic data submission and is electronically submitting production data data generated through clinical processes involving patient care to the public health agency or clinical data registry).
- Pew supports the requirement for MIPS eligible clinicians to submit their level of active engagement;
- Pew supports an increase in points allocated to the Public Health and Clinical Data Exchange (CDE) Objective; and
- Pew additionally recommends requiring the submission of the syndromic surveillance reporting measure in addition to the immunization registry reporting and electronic case reporting measures currently required.

• Health Information Exchange (HIE) Objective

• Pew supports the addition of an alternative, attestation-based measure for enabling exchange under the Trusted Exchange Framework and Common Agreement (TEFCA).

Pew further recommends that CMS continue and expand efforts to (1) mandate or otherwise support adherence to guidelines and standards in partnership with the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Disease Control and Prevention (CDC); and (2) specify that any reporting measures must also consider completeness of data, as part of improving the quality of electronic data reporting to public health agencies.

Proposed Changes to the Promoting Interoperability Performance Category under MIPS

Requiring Active Engagement and Increasing Points for Public Health and CDE Measure within Public Health and Clinical Data Exchange Objective

Pew applauds CMS' recognition of important efforts that should continue in order to effectively move providers and health care organizations toward electronically submitting data to public health agencies. Public health authorities obtain critical data from health care organizations through case reporting, lab

reporting, syndromic surveillance, and sharing of vaccination information. Requiring electronic reporting for certain public health objective measures in earlier years has clearly yielded major improvements to public health agencies' surveillance efforts. For example, when electronic lab reporting was required in Stage 2 of the Meaningful Use program, 92% of hospitals reported sending lab results electronically to public health agencies—compared to the 55% that reported doing so in the prior program stage, when electronic lab reporting was not yet a required measure.¹ Immunization reporting was also a required measure in Stage 2 of Meaningful Use.² As providers participating in the program advanced from Stage 1 to Stage 2 over the course of several program years, reporting to the immunization registry measure increased by almost half.³

Not all providers are involved in active electronic data exchange with public health agencies despite having technology with the capability to send information using automated, standard mechanisms. In 2019, about 65% of office-based physicians engaged in electronic health information exchange with providers outside their organization.⁴ However, about 12% of office-based physicians electronically exchanged patient health information with public health agencies.⁵ Pew agrees with CMS that knowing the level of active engagement, by requiring MIPS eligible clinicians to submit this detail, will help to identify gaps in progress and inform efforts to address them. Pew supports the concept of limiting the duration of primary levels of active engagement per reporting period to incentivize the increased utilization of electronic exchange by MIPS eligible clinicians; however, Pew recognizes that additional phase-in time and technical assistance may be necessary for some MIPS eligible clinicians to fully meet this requirement. Pew previously recommended increasing the weighting of the Public Health and Clinical Data Exchange Objective from 10 to 20 points and supports the steps CMS is taking to reflect the value of this objective.⁶

Requiring Syndromic Surveillance Reporting

Some outpatient physicians, such as those who practice at urgent care facilities, have meaningful syndromic surveillance data that would substantially benefit public health agencies. Syndromic surveillance reporting provides public health officials with data on a range of public health issues that can help create situational awareness before they become crises.⁷ Requiring the syndromic surveillance reporting measure under MIPS would (1) better align with the analogous Promoting Interoperability Program requirement in the Fiscal Year 2022 Medicare Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Long-term Care Hospital Prospective Payment System final rule; and (2) public health agencies to expand the data sources they receive. Given the significance to current and future public health efforts, it is important for CMS to continue to support the transition to syndromic data reporting in the final rule.

Additional Considerations for Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

Pew highlights the importance of ensuring public health data reporting from these providers, based on their reach and scope of practice. There are over 355,000 licensed nurse practitioners,⁸ 125,000 physician assistants in clinical practice,⁹ and 70,000 clinical nurse specialists in the United States.¹⁰ Furthermore, 7 out of 10 nurse practitioners deliver primary care and estimated annual patient visits for nurse practitioners exceeds 1.06 billion.¹¹ In the progress toward improved, timely, and complete public health reporting, it is critical to expand provider participation in the Promoting Interoperability performance category to address circumstances where relevant data from these providers is not currently reaching public health agencies through electronic reporting. Given this, Pew supports the concept of discontinuing the reweighting policy for the CY 2023 performance period/CY 2025 MIPS payment year.

Enabling Exchange under TEFCA via a Measure within the HIE Objective

Pew believes CMS' proposed new measure within the HIE Objective is one important step in increasing provider engagement in the successful implementation of nationwide bidirectional health information exchange. Bidirectional exchange means that data is shared between EHRs and other systems, and that providers can both view and incorporate information into EHRs. This ensures that critical clinical data becomes part of the medical record, regardless of where a patient received care. Without these connections, health information will remain segmented, meaning providers may continue to struggle to access complete patient data on a timely basis—which can lead to medication errors and expensive duplicative testing, among other risks.¹²

The principles for nationwide health information exchange laid out in TEFCA reflect a network-ofnetworks structure and allow connections at different levels through a single on-ramp, for a wide range of entities.¹³ While much work remains to implement and fulfill the vision of TEFCA, particularly for public health agencies,¹⁴⁻¹⁵ stakeholders have acknowledged its potential benefits for public health in fostering interjurisdictional data exchange, reducing costs associated with connecting to multiple, different networks, and improving availability of quality data.¹⁶⁻¹⁷

Incentivizing engagement in health information networks may help increase provider reporting; as more providers and health care organizations exchange information, patients will have more comprehensive records, providers can access more complete information to support their care, and public health agencies have opportunities to connect with important sources of data. As the current COVID-19 pandemic demonstrates, integrated and comprehensive medical records are essential for ensuring the delivery of appropriate care and preventative measures.

Pew agrees that including an additional measure for a MIPS eligible clinician to earn credit for the HIE Objective by connecting to a qualified health information network (either directly or indirectly) would incentivize participation in TEFCA. This will continue to support bidirectional information exchange in a flexible manner that reflects broader federal progress toward increasing opportunities to enable exchange under TEFCA. Pew appreciates ongoing CMS' efforts to encourage and increase participation in bidirectional information exchange, and the agency should include this measure in the final rule as written.

The proposed updates to the Promoting Interoperability performance category will provide additional incentives for providers to use existing electronic data exchange capabilities and improve public health data for COVID-19 and future threats. In future efforts, CMS can go further to ensure that public health agencies receive timely and complete data. Pew recommends the future implementation of more robust public health measures with numerators and denominators that enable opportunities to fully quantify quality data exchange. Pew previously noted it was undertaking a process to identify more robust quality data measures.⁶ Pew has since submitted conceptual candidate measures for CMS consideration and looks forward future engagements with CMS and other stakeholders to refine these measures through further specification and testing.

Additional Considerations

Addressing Health Equity

While public health authorities rely on data from health care providers, major gaps remain in the timeliness and completeness of this data.¹⁸⁻¹⁹ These gaps have hindered the comprehensive actions necessary for a swift, timely response throughout the COVID-19 pandemic. For example, from early COVID-19 vaccine reporting, data on race and ethnicity is present in only 51.9% of cases.²⁰ Manual case

reporting, or the non-electronic transmission of results through modalities such as faxes, also results in significant delays and widespread under-reporting.²¹ Without this information, officials cannot adequately track the spread of a public health threat or understand its impact on different communities, or advance broader commitments to improve health equity for historically underserved populations.²²

The collection and transmission of complete data can be a key component to address health equity.²³ In 2017, about 69% of office-based physicians reported electronically recording data on social determinants of health.⁵ However, using manual, outdated data collection mechanisms in public health data reporting both increases the risk of human error and can allow for the omission of important information that physicians currently collect. Increasing electronic data-sharing with public health agencies can help ensure that health officials have better data to improve decision-making, enhance effective disease surveillance and response, and meaningfully address disparities. CMS can encourage hospitals and providers to use these reporting tools by requiring quality data submission for reimbursement. CMS can also coordinate with the ONC to mandate that EHR vendors build in functions that let providers collect and report electronic, standardized, and demographically detailed data.

Specifying that reporting must be complete, and mandate adherence to specific standards in partnership with ONC.

Completeness of race and ethnicity data is critical to support health equity, both during a crisis like the COVID-19 pandemic and for other reportable conditions that pose longer-term challenges. Additionally, complete information on reporters, providers, performing facilities, and specimen type is integral to timely public health investigation and follow-up activities. The development of more robust measures could help assess compliance more easily. To improve the completeness of submitted data, CMS should also work with ONC to identify new standards, where appropriate, and require adherence to existing ones. Where they already exist—often as Health Level 7 implementation guides—adherence to such standards should be required to meet the Promoting Interoperability measures.

The COVID-19 pandemic highlighted gaps in data exchange that limited the effectiveness of public health response and reduced the impact of existing technologies. Through the proposed updates to the Promoting Interoperability performance category, CMS will help to increase adoption of electronic reporting to public health agencies. Additionally, these connections should follow national standards and send all of the data elements that public health officials need—such as phone number, address, race, and ethnicity—to conduct contact tracing, investigate cases, assess disparities, and track the efficacy of treatments or vaccine distribution.

Promoting interoperability efforts can provide the necessary incentives to spur national adoption of public health data exchange and ensure that providers and public health agencies are exchanging vital data needed to safeguard and improve public health.

Comments Related to Medicare coverage of opioid use disorder services furnished by opioid treatment programs and electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act)

The proposed CMS provisions in these regulations will continue to expand access to evidence-based treatment for patients with substance use disorder via telehealth. CMS is also proposing an update to the opioid treatment program (OTP) bundle to allow OTPs to be paid for services delivered at mobile units, which would help provide Medicare enrollees convenient access to methadone for OUD—which can only be delivered by OTPs.

Pew supports the proposed regulations being updated to address the growing need for OUD treatment among Medicare beneficiaries. The OUD prevalence rate for Medicare beneficiaries more than tripled between 2013 and 2018, and the average age of admissions for substance use treatment has also increased.²⁴ Medications for opioid use disorder (MOUD) remain the standard of care for older adults.²⁵ However, only a minority of people who would benefit from this treatment receive it—in 2020, less than 16% of all Medicare beneficiaries with OUD received medication.²⁶ The proposed regulations will help fill that gap.

Pew also supports CMS' planned data collection on these services through CY2023, which will inform decisions regarding their inclusion as permanent additions to Medicare's telehealth services, to the extent allowed under federal law.

The Physician Fee Schedule rule changes will maintain and improve access to OUD treatment by continuing access to buprenorphine treatment furnished through telehealth, including use of audioonly means, and supporting access to methadone for Medicare beneficiaries. Specifically, the proposed rule makes updates to:

- Continue delaying in-person visit requirements for mental health services furnished via telehealth,
- Continue allowing payment to rural health clinics (RHCs) and federally qualified health centers (FQHCs) for furnishing telehealth services,
- Continue allowing certain services to be furnished via audio-only telecommunications systems,
- Continue allowing telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home, and
- Clarify that OTPs can bill Medicare for medically reasonable and necessary services furnished via mobile units in accordance with SAMHSA and DEA rules and guidance.²⁷

Delayed In-person Visit Requirements for Mental Health Services

Pew supports continuing to delay the requirement that there be an in-person visit with a provider six months before an initial mental health telehealth service. However, while Pew understands that this provision is meant to include substance use disorder services, including the initiation of treatment with buprenorphine, this is not clear in the proposed rule. Additionally, the fee schedule as-written continues to delay the in-person visit requirement for OTPs only until the end of the PHE, and not for an additional 151 days, the standard for other providers.

Shortly after the COVID-19 PHE declaration, the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) provided regulatory flexibilities allowing health care practitioners to prescribe buprenorphine to patients with OUD using

telehealth, without first conducting an in-person evaluation.²⁸ As a result of these administrative actions, buprenorphine is the only FDA-approved medication for OUD that can be prescribed without an in-person visit to a doctor or treatment facility during the on-going pandemic.

A review of the recent literature on the delivery of MOUD—primarily buprenorphine—via telehealth found that, although there has not yet been a trial comparing in-person opioid treatment to virtual care, and long-term outcomes are currently unavailable, the existing research does indicate promising findings that favor telehealth delivery such as high rates of patient retention, and low rates of continued substance use.²⁹ Many Medicare beneficiaries have taken advantage of this option. Between March 2020 and May 2021, more than 14% of buprenorphine initiations for people with fee-for-service coverage was via telemedicine.³⁰

Recommendations:

- CMS should continue to delay the requirement for an in-person visit prior to telehealth services so that Medicare beneficiaries can continue initiating MOUD from home. The final PFS should clarify that this rule applies to the initiation of buprenorphine for OUD treatment.
- CMS should revise the PFS to clarify that this coverage will remain in place for services delivered by OTPs as long as SAMHSA and DEA rules allow, rather than until the end of the PHE. If the agencies continue these flexibilities using other methods, such as the opioid crisis PHE, this will support continued access to telemedicine for people receiving services from OTPs.³¹

Payment for Telehealth Services furnished by RHCs and FQHCs

Pew supports the continuation of payment to rural health centers (RHCs) and federally qualified health centers (FQHCs) for telehealth services. RHCs and FQHCs are a critical part of the OUD treatment infrastructure. As of 2019, 64% of FQHCs provided some form of MOUD—most commonly, buprenorphine.³²

Many Medicare enrollees access care through these sites. In 2021, 11% of patients served by FQHCs had Medicare coverage.³³ And, compared to Medicare enrollees who don't access these sites, these patients are twice as likely to have an SUD, and are more likely to be non-white, disabled, or eligible for Medicaid.³⁴ In rural areas, providers report that transportation is one of the most common barriers to serving patients with Medicare. ³⁵ Telehealth helps fill in the gaps - according to the Office of the Assistant Secretary for Planning and Evaluation, telehealth visits by rural FHQCs and RHCs increased from 9,000 in 2019 to over 830,000 in 2020.³⁶

Recommendation:

• To ensure continued access to high quality care at these sites, telehealth services should continue to be covered under Medicare by these providers on the same basis as if the service were provided in-person (sustaining service parity), and these providers should continue to be reimbursed in the same manner or rate as if they were in-person services (sustaining payment parity).

Continued Use of Audio-only Communications Technology

Pew supports the continued coverage of certain services, including mental and behavioral health services, provided via audio-only telecommunications systems.

During the COVID-19 PHE, DEA and SAMHSA have permitted providers to prescribe buprenorphine to new and established patients with OUD via audio-only methods. These flexibilities support increased access to lifesaving treatment for people with OUD.

Audio-only telemedicine supports broader efforts to advance health equity because the use of video is not widely accessible for the many Americans living in "digital deserts" —14.5 million people as of 2019.³⁷ A recent study of a large integrated health system in Massachusetts found that patients who were 65 years and older, Black, Hispanic, and/or Spanish speaking, and/or living in areas with the lowest broadband internet access, lowest median income, and lowest educational attainment were less likely to use video visits than privately insured, White individuals living in areas with higher income and broadband access.³⁸ Of note, Medicare beneficiaries are among those who have used audio-only services most commonly for behavioral health needs. In 2020, 70% of all behavioral health telehealth visits among Medicare beneficiaries were audio only.³⁹

Recommendation:

• CMS should continue payment parity for audio-only telehealth services and should ensure that this parity extends to the 151-day period following the COVID-19 PHE.

Continued Allowance of Telehealth Services to be Furnished from Any Geographic or Originating Site

Pew commends CMS in its proposal to continue allowing providers to bill for substance use disorder treatment services delivered over telehealth from any originating site, including the patient's home, for an additional 151 days following the end of the public health emergency (PHE).

During the PHE, the telehealth flexibilities have supported life-saving continued access to OUD treatment. For example, the value of flexibility was demonstrated in New Jersey where in-depth interviews with MOUD treatment providers revealed that telehealth was seen as critical for removing barriers to treatment for patients with inadequate transportation or childcare, patients who lived far away from their providers, and patients with work schedules that did not allow for daytime appointments.⁴⁰

Transportation in particular is a common barrier for people with Medicare coverage. As of 2015, an estimated 2.3 million Medicare beneficiaries 65 and over were "transportation disadvantaged"—defined as being unable to participate in social activities or events during the last month because they didn't have a way to get there.⁴¹

Over the course of the COVID-19 pandemic, many people with Medicare coverage have embraced telemedicine as a method of health service delivery. In the first year, 43% used telehealth to receive at least one service.⁴² These services included behavioral health—during that time, 16% of all telehealth services in Medicare fee-for-services were for this purpose.⁴³

Coverage for Mobile OTP Services

Pew supports the Agency's proposal to provide coverage for mobile OTP services as a critical point of access to OUD treatment. Methadone, a medication approved to treat OUD by the FDA since 1972, is the most tightly restricted MOUD. The medication can be dispensed to patients only at state- and federally-regulated OTPs, often during daily in-person clinic visits. Methadone for OUD treatment can help patients manage withdrawal symptoms, reduce illicit opioid use, and stay in treatment.⁴⁴ Methadone has also been associated with reduced risk of death from opioid overdose and to reduce risky behaviors—such

as injection drug use—which can prevent the transmission of infectious diseases such as HIV and hepatitis C.⁴⁵

However, patients can face significant challenges in accessing methadone. Patients of OTPs typically have to travel farther to receive methadone than they do to access other medical care facilities (e.g., pharmacies, FQHCs), and studies of drive times to OTPs have found that, on average, patients in rural areas travel more than 45 minutes each way to access methadone.⁴⁶ These results indicate that the travel burden of daily visits can interfere with treatment retention and outcomes.

To help address this problem, in June 2021 the DEA published new rules permitting all OTPs to add mobile units to better serve their patients.⁴⁷ As of July 2022, at least one OTP has started offering services from a new mobile methadone unit.⁴⁸ By bringing methadone treatment closer to communities, mobile treatment services could help more people get care. According to the National Survey of Drug Use and Health, logistical barriers, including transportation, was a common reason Medicare beneficiaries with SUD did not receive treatment when they needed it.⁴⁹

Through this rule, CMS improves access to care for Medicare beneficiaries by clarifying that OTPs can bill Medicare for medically reasonable and necessary services furnished via mobile units in accordance with SAMHSA and DEA guidance.

There is mounting evidence of the effectiveness in allowing the use of buprenorphine initiation and treatment via telehealth, and methadone is a critical part of the treatment system. The proposed changes included in the draft rule will help Medicare beneficiaries receive evidence-based, life-saving treatment for OUD. Pew commends CMS in extending these rule changes.

¹ Office of the National Coordinator for Health Information Technology, "Hospital Selection of Public Health Measures in Medicare EHR Incentive Program," November 2016,

https://dashboard.healthit.gov/quickstats/pages/FIG-MU-Hospitals-Public-Health-Measure-Attestations.php. ² Centers for Medicare & Medicaid Services, "Stage 2 Overview Tipsheet," August 2012, https://www.cms.gov/regulations-and-

guidance/legislation/ehrincentiveprograms/downloads/stage2overview_tipsheet.pdf.

³ The Office of the National Coordinator for Health Information Technology, "Electronic Reporting to Immunization Information Services (IIS) among Medicare Eligible Professionals, 2011-2014," July 2015,

https://dashboard.healthit.gov/quickstats/pages/medicare-eps-immunization-registry-reporting-trend.php.

⁴ Y. Pylypchuk et al., "Interoperability Among Office-Based Physicians in 2015, 2017, and 2019," *ONC Data* Brief (July 2022) no.59, https://www.healthit.gov/data/data-briefs/interoperability-among-office-based-physicians-2019.

⁵ C. Richwine et al., "Electronic Public Health Reporting & Recording of Social & Behavioral Determinants of Health Among Office-Based Physicians, 2019," *ONC Data Brief* (August 2022) no.60, <u>https://www.healthit.gov/data/data-briefs/electronic-public-health-reporting-recording-social-behavioral-determinants-health.</u>

⁶ The Pew Charitable Trusts, "Pew Urges Federal Government to Prioritize Better Sharing of Health Data," June 2021, <u>https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2021/06/28/pew-urges-federal-government-to-prioritize-better-sharing-of-health-data.</u>

⁷ National Association of County and City Health Officials, "The *Forces of Change* in America's Local Public Health System," November 2018, <u>https://www.naccho.org/uploads/downloadable-resources/2018-Forces-of-Change-Main-</u>Report.pdf.

⁸ American Association of Nurse Practitioners, "Nurse Practitioner Fact Sheet," April 2022, https://storage.aanp.org/www/documents/NPFacts 40722.pdf.

⁹ R.S. Hooker and J.F. Cawley, "Physician Assistants/Associates at 6 Decades," *American Journal of Managed Care* (November 2021) 27(11):498-504, <u>https://www.ajmc.com/view/physician-assistants-associates-at-6-decades</u>.
¹⁰ National Association of Clinical Nurse Specialists, "Unlocking the Mystery of the Clinical Nurse Specialist,"

April 2018, https://nacns.org/wp-content/uploads/2018/04/Fact-or-Fiction-FINAL-4-23-18.pdf.

¹¹ American Association of Nurse Practitioners, "Nurse Practitioner Infographic," April 2022, https://storage.aanp.org/www/documents/NP_Infographic_040822.pdf.

¹² R.S. Huckman and M. Uppaluru, "The Untapped Potential of Health Care APIs," *Harvard Business Review*, December 2015, https://hbr.org/2015/12/the-untapped-potential-of-health-care-apis.

¹³ The Office of the National Coordinator for Health Information Technology, "Common Agreement for Nationwide Health Information Interoperability Version 1," January 2022,

https://www.healthit.gov/sites/default/files/page/2022-

01/Common Agreement for Nationwide Health Information Interoperability Version 1.pdf.

¹⁴ N. Arzt, "TEFCA: A Public Health Perspective," February 2018, <u>https://www.hln.com/tefca-a-public-health-perspective/</u>.

¹⁵ N. Arzt, "ONC Finally Releases TEFCA: What it Might Mean to Public Health," January 2022, <u>https://www.hln.com/tefca-v1/</u>.

¹⁶ Association of Public Health Laboratories, "Comments on the Draft Trusted Exchange Framework and Common Agreement," February 2018,

https://www.aphl.org/programs/informatics/Documents/Comments%20on%20the%20Drafted%20Trusted% 20Exchange%20Framework%20and%20Common%20Agreement.pdf.

¹⁷ American Immunization Registry Association, "Public Comment of Draft Trusted Exchange Framework and US Core Data for Interoperability," February 2018,

https://repository.immregistries.org/files/resources/5a85e9510ecfe/aira_letter_and_comments_-_trusted_exchange_framework_final_new_logo-1.pdf.

¹⁸ B.E. Dixon et al., "Completeness and Timeliness of Notifiable Disease Reporting: A Comparison of Laboratory and Provider Reports Submitted to a Large County Health Department," *BMC Medical Informatics and Decision Making* (June 2017) 17:87, <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5481902/</u>.

¹⁹ N. Adekoya et al., "Completeness of Reporting of Race and Ethnicity data in the Nationally Notifiable Diseases Surveillance System, United States, 2006-2010," *Journal of Public Health Management and Practice* (March 2015) 21(2): E16-E22, <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708284/</u>.

²⁰ E.M. Painter et al., "Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program," *Morbidity and Mortality Weekly Report* 70, no. 5 (February 2021) 174-77,

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7005e1-H.pdf.

²¹ E.E. Sickbert-Bennett et al., "Completeness of Communicable Disease Reporting, North Carolina, USA, 1995-1997 and 2000-2006," Emerging Infectious Diseases (January 2011) 17(1):23-29,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3204630/. ²² The White House, "Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," January 2021, https://www.whitehouse.gov/briefingroom/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-

communities-through-the-federal-government/. ²³ The Pew Charitable Trusts, "Quality Data Plays Key Role in Defining and Addressing Health Inequities," July 2022, https://www.pewtrusts.org/en/research-and-analysis/articles/2022/07/08/quality-data-plays-keyrole-in-defining-and-addressing-health-inequities.

²⁴ A.M. Carew and C. Comiskey, "Treatment for Opioid Use and Outcomes in Older Adults: A Systematic Literature Review," Drug and Alcohol Dependence 182 (2018): 48-57,

https://www.sciencedirect.com/science/article/pii/S0376871617305367; C. Shoff, T.C. Yang, and B.A. Shaw, "Trends in Opioid Use Disorder among Older Adults: Analyzing Medicare Data, 2013-2018," Am J Prev Med 60, no. 6 (2021): 850-55, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8154702/.

²⁵ A. Dufort and Z. Samaan, "Problematic Opioid Use among Older Adults: Epidemiology, Adverse Outcomes and Treatment Considerations," Drugs Aging 38, no. 12 (2021): 1043-53,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8421190/.

²⁶ U.S. Department of Health and Human Services, Office of Inspector General, "Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder" (2021), https://oig.hhs.gov/oei/reports/OEI-02-20-00390.pdf.

²⁷ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 FR 11008 (Feb. 26, 2020), https://www.federalregister.gov/documents/2020/02/26/2020-03627/registration-requirements-for-narcotic-

treatment-programs-with-mobile-components; Substance Abuse and Mental Health Services Administration, "Letter to OTP Directors, SOTAs, and State Directors on Mobile Component," September 29, 2021,

https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf.

²⁸ U.S. Drug Enforcement Administration, "Letter to DEA Qualifying Practitioners, DEA Qualifying Other Practitioners" (2020), https://www.deadiversion.usdoi.gov/GDP/(DEA-DC-

022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf; Substance Abuse and Mental Health Services Administration, "FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency" (2020),

https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

²⁹ H. Mahmoud et al., "Telehealth-Based Delivery of Medication-Assisted Treatment for Opioid Use Disorder: A Critical Review of Recent Developments," Current Psychiatry Reports (2022), https://doi.org/10.1007/s11920-022-01346-z.

³⁰ S.Y. Patel et al., "Patient and Clinician Characteristics Associated with Use of Telemedicine for Buprenorphine Induction among Medicare Beneficiaries," Journal of General Internal Medicine (2022), https://doi.org/10.1007/s11606-022-07633-y.

³¹ B.C.E. Dooling and L. Stanley, "Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Telemedicine & Initiating Buprenorphine Treatment" (The George Washington University, 2021), https://regulatorystudies.columbian.gwu.edu/telemedicine-initiating-buprenorphine-treatment.

³² B. Corallo et al., "Community Health Centers and Medication-Assisted Treatment for Opioid Use Disorder" (Kaiser Family Foundation, 2020), https://www.kff.org/uninsured/issue-brief/community-health-centers-andmedication-assisted-treatment-for-opioid-use-disorder/.

³³ U.S. Department of Health and Human Services, Health Resources & Services Administration, "2021 Patient Characteristics Snapshot," accessed 8/215/2022, https://data.hrsa.gov/tools/data-reporting/data-snapshot.

³⁴ T.A. Lavelle et al., "Utilization of Health Care Services among Medicare Beneficiaries Who Visit Federally Qualified Health Centers," BMC Health Services Research 18 (2018): 41, https://doi.org/10.1186/s12913-018-2847-

 $\frac{x}{35}$ M. Lahr et al., "Barriers to Health Care Access for Rural Medicare Beneficiaries: Recommendations from Rural Health Clinics" (University of Minnesota Rural Health Research Center, 2021), https://rhrc.umn.edu/wpcontent/uploads/2021/01/UMN-RHC-Access-to-Care-PB 1.20.pdf.

³⁶ L.W. Samson et al., "Medicare Beneficiaries" Use of Telehealth in 2020: Trends by Beneficiary Characteristics

and Location" (Office of the Assistant Secretary for Planning and Evaluation, 2021),

https://aspe.hhs.gov/reports/medicare-beneficiaries-use-telehealth-2020.

³⁷ Federal Communications Commission, "FCC Annual Broadband Report Shows Digital Divide Is Rapidly Closing" (2021), <u>https://www.fcc.gov/document/fcc-annual-broadband-report-shows-digital-divide-rapidly-closing</u>; Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities through the Federal Government, 86 Fed. Reg. 7009-13 (January 20, 2021),

https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-forunderserved-communities-through-the-federal-government.

³⁸ J.A. Rodriguez et al., "Differences in the Use of Telephone and Video Telemedicine Visits During the Covid-19
Pandemic," *The American Journal of Managed Care* 27, no. 1 (2021), <u>https://doi.org/10.37765/ajmc.2021.88573</u>.
³⁹ Samson et al., "Medicare Beneficiaries' Use of Telehealth in 2020."

⁴⁰ P.C. Treitler et al., "Perspectives of Opioid Use Disorder Treatment Providers During COVID-19: Adapting to Flexibilities and Sustaining Reforms," *J Subst Abuse Treat* 132 (2022): 108514, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8630075.

⁴¹ M. Ryvicker, E. Bollens-Lund, and K.A. Ornstein, "Driving Status and Transportation Disadvantage among Medicare Beneficiaries," *J Appl Gerontol* 39, no. 9 (2020): 935-43, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6486463/.

⁴² U.S. Department of Health & Human Services, Office of Inspector General, "Telehealth Was Critical for Providing Services to Medicare Beneficiaries During the First Year of the Covid-19 Pandemic" (2022), https://oig.hhs.gov/oei/reports/OEI-02-20-00520.asp.

⁴³ Ibid.

⁴⁴ M.K. Greenwald, "Heroin Craving and Drug Use in Opioid-Maintained Volunteers: Effects of Methadone Dose Variations," *Experimental and Clinical Psychopharmacology* 10, no. 1 (2002): 39-46, <u>https://doi.org/10.1037//1064-1297.10.1.39</u>; W. Ling et al., "A Controlled Trial Comparing Buprenorphine and Methadone Maintenance in Opioid Dependence," *Archives of General Psychiatry* 53, no. 5 (1996): 401-07,

https://jamanetwork.com/journals/jamapsychiatry/article-abstract/497574; A. Fareed et al., "Effect of Methadone Maintenance Treatment on Heroin Craving, a Literature Review," *Journal of Addictive Diseases* 30, no. 1 (2011): 27-38, https://doi.org/10.1080/10550887.2010.531672.

⁴⁵ R.P. Mattick et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence," *Cochrane Database of Systematic Reviews* CD002209, no. 3 (2009),

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002209.pub2/abstract; D.S. Metzger et al., "Human Immunodeficiency Virus Seroconversion among Intravenous Drug Users in- and out-of-Treatment: An 18-Month Prospective Follow-Up," *Journal of Acquired Immune Deficiency Syndromes* 6, no. 9 (1993): 1049-56, https://pubmed.ncbi.nlm.nih.gov/8340896/; R.P. Schwartz et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995-2009," *American Journal of Public Health* 103, no. 5 (2013): 917-22,

https://www.ncbi.nlm.nih.gov/pubmed/23488511; L. Sordo et al., "Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies," *BMJ* 357 no. 8103 (2017): j1550, https://pubmed.ncbi.nlm.nih.gov/28446428/, J.I. Tsui et al., "Association of Opioid Agonist Therapy with Lower Incidence of Hepatitis C Virus Infection in Young Adult Injection Drug Users," *JAMA Internal Medicine* 174, no. 12 (2014): 1974-81, https://www.ncbi.nlm.nih.gov/pubmed/25347412; S.E. Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder," *JAMA Network Open* 3, no. 2 (2020): e1920622, https://www.ncbi.nlm.nih.gov/pubmed/32022884.

⁴⁶ P.J. Joudrey et al., "Pharmacy-Based Methadone Dispensing and Drive Time to Methadone Treatment in Five States within the United States: A Cross-Sectional Study," *Drug Alcohol Depend* 211 (2020): 107968, <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7529685/;</u> P.J. Joudrey, E.J. Edelman, and E.A. Wang, "Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 U.S. States," *JAMA* 322, no. 13 (2019): 1310-12, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6777265/.

⁴⁷ Drug Enforcement Administration, "DEA Finalizes Measures to Expand Medication-Assisted Treatment," news release, June 28, 2021, <u>https://www.dea.gov/press-releases/2021/06/28/dea-finalizes-measures-expand-medication-assisted-treatment</u>.

⁴⁸ G.W. Miller, "A First in Us, New Mobile Methadone Unit Seeks to Reduce Fatal Overdoses in RI," *The Providence Journal*, July 23, 2022, <u>https://www.providencejournal.com/story/news/healthcare/2022/07/23/rhode-island-mobile-methadone-unit-seeks-reduce-fatal-overdoses/10125640002/</u>.

⁴⁹ W.J. Parish et al., "Substance Use Disorders among Medicare Beneficiaries: Prevalence, Mental and Physical Comorbidities, and Treatment Barriers," *American Journal of Preventive Medicine* 63, no. 2 (2022): 225-32, https://www.sciencedirect.com/science/article/pii/S0749379722001040.