Federal and State Policy Levers to Maintain Access to MOUD During the Covid-19 Pandemic

Foundation for Opioid Response Efforts
Manatt Health Strategies
National Academy for State Health Policy
Introduction

Karen A. Scott, MD, MPH
President, Foundation for Opioid Response Efforts

Follow ongoing updates on our website:
https://www.ForeFdn.org
Agenda

1. Welcome and Webinar Logistics
2. Foundation for Opioid Response Efforts
   - Introduction to FORE
   - FORE COVID-19 National Emergency Response
   - Manatt & NASHP Introductions
3. Background
4. Policy Options for Provision of MOUD During COVID-19
   - Telehealth
   - Buprenorphine
   - Methadone
   - Psychosocial Counseling
   - Clear and Consistent Communication
5. Question and Answer Session with: Jocelyn Guyer, MPP
   Jodi Manz, MSW
   Hannah Snyder, MD
Webinar Logistics

1. Webinar is being recorded and will be on www.ForeFdn.org shortly after the session ends.

2. Presentation slides will be made available for download on our website.

3. Please use the “Q&A” found at the bottom of your Zoom screen.
   A. If you have a similar question, please upvote using the thumbs up button on the question.
   B. We will read as many questions live as time permits.

4. An FAQ will be provided on our website based on the questions submitted during the Q&A session.

5. Any resources you would like to share with everyone please send to info@ForeFdn.org

6. There will be a brief survey immediately following the webinar. Please provide us with feedback!
About FORE

Founded in 2018, the Foundation for Opioid Response Efforts (FORE) is a 501(c)(3) private, national, grantmaking foundation focused on supporting solutions to the opioid crisis.

FORE’s mission is to convene and support partners advancing patient-centered, innovative, evidence-based solutions impacting people experiencing opioid use disorder, their families, and their communities.

FORE is committed to funding a diversity of projects that contribute solutions to the crisis at national, state, and community levels.

• Inaugural RFP: Access to Treatment for Vulnerable Populations
  • 19 Grants Awarded: https://ForeFdn.org/our-grantees/
FORE’s COVID-19 National Emergency Response

• FORE is looking for ways to provide broad assistance during this time of uncertainty
• Up-to-date Resources
• Webinars:
  • Weekly series
  • Thursdays @3pm ET
• Facilitating connections with experts and technical assistance
• Submit your ideas

Follow updates on our website: www.ForeFdn.org
Webinar Panel

Jocelyn Guyer, MPP
Managing Director, Manatt Health Strategies

Jodi Manz, MSW
Project Director, Chronic and Vulnerable Populations
National Academy for State Health Policy (NASHP)
Background

Jocelyn Guyer, MPP
Managing Director, Manatt Health Strategies

Follow ongoing updates on our website:
https://www.manatt.com/COVID-19
Disclaimers and Caveats

- Rapidly changing policy and regulatory environment
- States and localities have significant flexibility in how they respond; providers need to check with them directly for the latest on specific issues
- Many questions remain unanswered; policymakers will vary in risk tolerance for action without clear answers
- Some options and sources of flexibility are temporary and linked to the public health emergency and national emergency; others are long-standing (often forgotten) statutory and regulatory options
Individuals with OUD Are Particularly Vulnerable During COVID-19

Opioid use effects on respiratory and pulmonary health may increase risk and severity of COVID-19

Are more likely to experience homelessness or incarceration than those in the general population which increases risk of COVID-19

May be more likely to overdose when using substances alone

It is vital that they remain engaged in and can consistently access necessary medication for their OUD through methods that support social distancing

Source: COVID-19: Potential Implications for Individuals with Substance Use Disorders, NIDA, March 12, 2020
Reorienting MOUD to Meet the Aims of Social Distancing

- Maximize use of telemedicine/telephone to allow treatment to continue
- Promote flexible access to buprenorphine and methadone, including through home delivery
- Recognize and address importance of peer supports and counseling
- Maintain and adapt harm reduction efforts
- Support frontline providers
- Communicate clearly with OUD providers and patients throughout COVID-19

Today, our goal is to review policy options for supporting these objectives, focusing on MOUD and related counseling

Key Federal Agencies Involved in Regulating MOUD

<table>
<thead>
<tr>
<th>Agency</th>
<th>Oversight Responsibility</th>
<th>Select Flexibilities for COVID-19</th>
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</thead>
<tbody>
<tr>
<td>Substance Abuse and Mental Health Services Administration</td>
<td>• Oversees accreditation and certification for opioid treatment programs (OTPs)</td>
<td>• Extending take home doses for methadone</td>
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<td></td>
<td>• Works with DEA to regulate certain MOUD</td>
<td>• Part 2 medical emergency exception clarification</td>
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<tr>
<td>Drug Enforcement Administration (DEA)</td>
<td>• Oversees controlled substances</td>
<td>• Exception for OTP deliveries*</td>
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<tr>
<td></td>
<td></td>
<td>• Telehealth exception for in-person visit for controlled substances prescription*</td>
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<tr>
<td>Office of Civil Rights, (OCR) Department of Health and Human Services</td>
<td>• Oversees aspects of data privacy</td>
<td>• Enforcement discretion on the Health Insurance Portability and Accountability Act (HIPAA)</td>
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<tr>
<td>Centers for Medicare and Medicaid Services (CMS)</td>
<td>• Oversees Medicare and Medicaid programs, including coverage and reimbursement of MOUD</td>
<td>• Expansion of telehealth services for Medicare beneficiaries</td>
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<td>• New flexibility to waive prior authorization and cost sharing requirements via simplified means*</td>
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*Indicates state action may be necessary to use new federal flexibility

Depending on the issue, federal agencies have developed new guidance, issued clarifications or have indicated that they will use enforcement discretion.
## Select Levers for States to Take Advantage of Flexibilities

<table>
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<tr>
<td><strong>1135 Waivers</strong></td>
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<tr>
<td>- Allows states to waive or modify certain Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) requirements under public health emergencies</td>
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<tr>
<td>- States can waive a number of requirements on a broad scale including:</td>
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<tr>
<td>- Conditions of participation or other certification requirements</td>
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<tr>
<td>- Provider licensure requirements if provider is licensed in another state</td>
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<tr>
<td>- Program participation and similar requirements</td>
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<tr>
<td>- Prior authorization requirements</td>
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<tr>
<td><strong>1115 Waivers</strong></td>
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<tr>
<td>- Broad authority that allows states to waive Medicaid provisions</td>
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<tr>
<td>- Special disaster opportunity allows states to waive federal rules to streamline enrollment into long-term care programs and home and community-based services, as well as access broad authorities to vary and target services based on population needs</td>
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<tr>
<td><strong>Appendix K</strong></td>
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<tr>
<td>- Section 1915(c) Waiver Appendix K (“Appendix K”) is a longstanding federal authority that helps states streamline and expedite changes to their 1915(c) home and community-based services (HCBS) waivers to prepare for and respond to emergencies</td>
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<tr>
<td><strong>Federal Legislation</strong></td>
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<tr>
<td>- Can grant providers financial relief to absorb losses due to COVID-19, and provide additional flexibilities</td>
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<th>State Flexibilities</th>
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<td><strong>Emergency Declaration</strong></td>
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<tr>
<td>- Allows governors additional flexibilities to waive program requirements</td>
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<td><strong>Policy Change</strong></td>
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<tr>
<td>- States can update their Medicaid and state policies to allow for greater flexibility, including through State Plan Amendments</td>
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State Guidance and Provider Bulletins

States are also using guidance and bulletins to inform providers of flexibilities and expectations to facilitate a coordinated response

Opportunities for States to Inform Providers

- Many states are providing guidance to providers on:
  - Essential behavioral health providers that must remain open
  - Flexibilities for service delivery
  - Areas of enforcement discretion
- States are also asking behavioral health providers to develop and communicate an up-to-date disaster plan, including:
  - Protocols for contacting state COVID-19 response leads
  - Identifying and isolating patients who are sick or appear symptomatic
  - Locating alternative sites of care
  - Protocols for updating patients

Opportunities for Providers to Inform Patients

- Identify and communicate emergency contacts at provider practice sites to patients
- Identify and communicate alternate sites of care and prescribing partners

State Examples

- **Connecticut** released guidance to providers on leveraging telehealth for behavioral health, as well as for safely providing in-person behavioral health services when necessary.
- **Maryland** released guidance for recovery homes that details social distancing recommendations, medication storage, and how to care for household members with COVID-19 who do not require hospitalization.
- **Ohio** released comprehensive COVID-19 guidance, including on funding opportunities to support telehealth for behavioral health services, naloxone distribution, and supporting OTP facilities in maintaining services and isolating symptomatic patients.

Sources:
Policy Options for Provision of MOUD During COVID-19

Jocelyn Guyer, MPP
Managing Director, Manatt Health Strategies

Jodi Manz, MSW
Project Director, Chronic and Vulnerable Populations
National Academy for State Health Policy (NASHP)
Needed Elements for Successfully Delivering MOUD via Telehealth

- **Sufficient capacity of eligible providers** who can receive reimbursement for telehealth services

- **Telehealth technology infrastructure** that conforms with state and federal rules, including new flexibility under emergency declaration

- **Financial and/or technical support for some practices** to make the conversion to telehealth (e.g., small or rural practices)

- **Clear privacy and security guidance for providers** to navigate HIPAA, Part 2 and other information sharing rules

- **Aligned Medicaid service codes and payment rates** to take advantage of maximum flexibility allowed under federal guidance

- **Updated MAT workflows and protocols** to take advantage of new MOUD-specific flexibility
Recent Federal Action and State Options: New Flexibility in Medicare

- “Eligible originating site” requirements have been waived by CMS, allowing telehealth services to be provided outside of rural settings and a patient’s home
  - Medicare will also now provide more flexibility to reimburse providers for telehealth services provided via telephone

- Per CMS, providers also no longer need to have an established relationship with a patient to deliver telehealth services in Medicare

- Per CMS, providers licensed in one state may provide services to Medicare patients in other states via telehealth
  - This flexibility allows providers to leverage out of state telehealth networks to meet surging demand for services

- Congress is currently considering a third COVID-19 bill that includes new flexibility for FQHCs and Rural Health Clinics to provide telehealth services under Medicare to patients at home

**Note:** New flexibilities apply nationwide for purposes of Medicare reimbursement until the emergency declaration is lifted. State-level policies may need to be reviewed/amended to take advantage of new flexibility (e.g., state licensure restrictions).

Sources:
Recent Federal Action and State Options: Privacy & Security Flexibility

• Per new OCR bulletin, penalties will not be imposed when providers use certain non-HIPAA compliant communications platforms to conduct telehealth visits
  – Providers may use certain non-public remote communication applications, such as FaceTime, Facebook Messenger video chat, Google Hangouts, or Skype
  – Applications explicitly not allowed under OCR guidance include: Facebook Live, Twitch, TikTok and similar video communications applications that are public facing

• Per existing SAMHSA policy, providers may disclose Part 2-protected substance use disorder (SUD) information without consent in medical emergencies
  – SAMHSA will defer to providers on determining whether a medical emergency exists
  – This policy will remain in effect beyond the emergency declaration

Note: HIPAA flexibilities are temporary until the emergency declaration is lifted; Part 2 exception is long-standing. State-level policies may need to be reviewed/amended to take advantage of new flexibility

Sources:
Recent Federal Action and State Options: Increased MOUD-Specific Flexibility

- Per DEA, schedule II-V controlled substances can be prescribed via telehealth visits without an initial in-person evaluation during the public health emergency
  - Telehealth visits must be conducted using an audio-visual, real-time, two-way interactive communication system (i.e., not telephone only).
  - States and providers will need to clearly communicate this policy, as SAMHSA and CMS are allowing telephone visits in other contexts.

- Per SAMHSA, new and existing OTP patients treated with buprenorphine can be treated via telehealth
  - Applies only during the public health emergency and if the OTP provider determines that an adequate evaluation can be accomplished via telehealth visit

- Per SAMHSA, existing OTP patients treated with methadone can be treated via telehealth
  - Existing patients that have already received an in-person medical evaluation may receive ongoing treatment via telehealth

**Note:** New flexibilities apply nationwide for purposes of Medicare reimbursement until the emergency declaration is lifted. State-level policies may need to be reviewed/amended to take advantage of new flexibility.

Sources:
https://www.deadiversion.usdoj.gov/coronavirus.html
Opportunities for States

• Since the outbreak, 36 states have amended, or are in the process of amending, Medicaid policies and submitting waivers to:
  – Mandate coverage and payment parity for telehealth
  – Expand the definition of “eligible originating site” to allow visits to be conducted at home
  – Expand the definition of allowable modalities of telehealth (i.e., video, phone, secure messaging)
  – Establish temporary Medicaid telehealth service codes
  – Amend state licensing requirements to expand the pool of providers allowed to deliver telehealth services, including out-of-state providers
  – Marshal resources to allow providers to implement telehealth capabilities in their practices

State Examples

• **North Carolina** issued Medicaid policy changes to:
  – Establish payment parity for telehealth services;
  – Expand list of eligible originating sites;
  – Expand eligible telehealth technologies (e.g., smart phones);
  – Expand the types of providers that can provide telehealth services (e.g., licensed clinical addiction specialists); and,
  – Eliminate the need for some prior authorizations and referrals.

• **Washington** received approval via an 1135 waiver to suspend behavioral health licensing and certification requirements to allow more providers to deliver Medicaid services.
  – The State also purchased Zoom licenses for some providers that lack telehealth capabilities.

• **Virginia’s** Medicaid agency issued a policy memo to:
  – Permit most behavioral health services to be delivered via telehealth, including telephone.
  – Waive a requirement that specific telehealth service codes be used to bill for prescribing medications via telehealth

Sources:
Manatt Insights analysis: [https://healthinsights.manatt.com](https://healthinsights.manatt.com)
https://www.cchpca.org/sites/default/files/2020-03/VIRGINIA%20MSR%202020-077-001-W%20Attachment%20COVID%2019%20MEMO%20V1.0%20dtd%20031920_0.pdf
States and Providers Can Promote Flexible Access to Buprenorphine

**State Policy Levers**

- Ensure that state regulations, and policies are clear and support flexibility for buprenorphine providers, including telemedicine/telephone access and increase in buprenorphine waiver capacity
- Requiring co-prescribing of naloxone
- Extending prescription length
- Removing prior authorization requirements for all forms of buprenorphine
- Removing cost-sharing

**Provider Actions**

- Ensure buprenorphine waivered providers are waivered to see the maximum number of individuals allowable, and those with waivered to see 100 patients can seek a temporary increase of up to 275 patients
- Leverage telehealth to the maximum extent possible, but provide a mechanism for in-person induction and maintenance
- Extend number of days of buprenorphine prescription
- Consider switching form of buprenorphine or to vivitrol as clinically indicated

**Spotlight on Virginia**

- Allows office based opioid treatment (OBOT) providers to prescribe buprenorphine products through telehealth without initial in-person visit
- Allows OBOTs to switch the form of MAT without in-person visit
- Advises providers to co-prescribe naloxone
- Asks select OBOTs to consider longer prescriptions for stable patients

Sources: [https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?impersonate=true&id={953807C3-219F-4F74-9B7B-886FEB1DA1FD}&vsId={5005F370-0000-C315-BD08-BE8E14C18755}&objectType=document&objectStoreName=VAPRODOS1](https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?impersonate=true&id={953807C3-219F-4F74-9B7B-886FEB1DA1FD}&vsId={5005F370-0000-C315-BD08-BE8E14C18755}&objectType=document&objectStoreName=VAPRODOS1)
Federal Requirements for Methadone Dispensing Have Temporarily Eased

Prescribers (Unchanged for COVID-19)
- Only licensed OTPs can dispense methadone
  - Mid-level practitioners can dispense methadone if under the supervision of a licensed practitioner if they are licensed under state law and registered under state and federal law to dispense opioid drugs

Telehealth v. In-Person
- **Induction**: Must be completed during an in-person visit
- **Maintenance**: Can be provided through telehealth in light of COVID-19

Take Home Doses
- **Stable Patients**: States may request blanket exceptions for patients to receive 28 days of take-home doses
- **Less Stable Patients**: States may request blanket exceptions for patients who are less stable, but can handle take-home doses of 14 days
- **Home Delivery**: Per the DEA exception, authorized OTP staff member, law enforcement officer, or national guard personnel may make a "doorstep" delivery of take-home medication in an approved lock-box

State regulations may be more stringent than federal requirements

Sources:
States and Providers Can Promote Flexible Access to Methadone

**State Policy Levers**

- Ensure that state regulations, policies and guidance are clear, consistent and support flexibility for OTPs while balancing diversion concerns:
  - Allow extended take-home doses and home delivery when appropriate
  - Require use of lock-boxes for take home doses
  - Require staggered hours and alternate dosing days
  - Require initiation of individuals in an individual setting
  - Require co-prescribing of naloxone

*Clinician discretion and judgement always required*

**Provider Actions**

- **For stable patients:** Dispense up to 28-day supply of take-home doses as clinically indicated

- **For less stable patients:** Dispense up to 14-day supply of take home doses as clinically indicated for patients who are less stable, but can handle take home doses of 14 days

- Leverage telehealth to the maximum extent possible and as clinically indicated

- Deliver doses to patients who cannot safely leave their homes

**Spotlight on Massachusetts**

- Aligns state policy with take home exceptions of 14 and 28 days
- Requires patients to have a lockbox to receive take home doses of methadone

Many states are aligning their take home exceptions with SAMHSA guidance, while other states (e.g., WA, CA, OH and NY) are tightening exceptions

Opportunities for States on Counseling and MOUD

- The COVID-19 pandemic has hastened state movement to ease linkages of counseling and MOUD
  - Authorize MOUD prescriptions to patients without requiring counseling visits
  - Allow and encourage counseling to be provided to patients, as necessary, via telehealth and telephone
  - States still can encourage use of counseling and peer support
    - Allow and encourage flexible delivery of peer supports services—which help promote recovery—through telehealth, online group platforms, and hotlines

Spotlight on States

- **Virginia**: Eliminated penalties to OBOTs for missed counseling that is usually provided alongside a buprenorphine prescription
- **West Virginia**: Suspended all counseling requirements for MOUD on a temporary basis
- **California**: Allows OTPs to provide counseling via telephone (telehealth requires approval by county) and to request blanket counseling exceptions from the state

Sources:

https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?impersonate=true&id={953807C3-219F-4F74-9B7B-886FEB1DA1FD}&vsId={5005F370-0000-C315-BD08-8E8E14C18755}&objectType=document&objectStoreName=VAPRODOS1
## Review of State Policy Levers

### State Medicaid Policy Levers

- Mandate coverage and payment parity for telehealth and in-person services
- Expand the definition of “eligible originating site” to allow visits to be conducted at home
- Expand the definition of allowable modalities of telehealth
- Establish temporary Medicaid telehealth service codes to align with new flexibilities
- Amend state licensing requirements to expand the pool of providers to deliver telehealth services, including out-of-state providers
- Marshal resources to allow providers to implement telehealth capabilities in their practices

### Telehealth

### Counseling

- Authorize MOUD prescriptions to patients without requiring counseling visits
- Allow and encourage counseling to be provided to patients, as necessary, via telehealth and telephone
- Allow and encourage flexible delivery of peer supports services—which help promote recovery—through telehealth, online group platforms, and hotlines
# Checklist of State Policy Levers and Provider Actions

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Take Care of Yourself!
Thank You For Your Work!
Questions?

Jocelyn Guyer, MPP
Managing Director, Manatt Health Strategies

Hannah Snyder, MD
Co-PI & Director of CA Bridge to Treatment
UCSF at Zuckerberg San Francisco General Hospital
Family Medicine and Addiction Medicine

Jodi Manz, MSW
Project Director, Chronic and Vulnerable Populations
National Academy for State Health Policy (NASHP)
Additional Resources

**SAMHSA** COVID-19 guidance and resources  
[https://www.samhsa.gov/coronavirus](https://www.samhsa.gov/coronavirus)

**Centers for Medicare & Medicaid Services** guidance, including a compilation of state 1135 waivers  

**American Society of Addiction Medicine** compilation of guidance and resources, including links to state-level policy actions and waiver requests  

**State Health & Value Strategies** resources on state policy options and responses  
[https://www.shvs.org/](https://www.shvs.org/)

**Manatt Health** resources on federal and state strategies to respond to COVID-19  

**National Academy for State Health Policy** resources on state activity  
[https://nashp.org/](https://nashp.org/)
About Manatt Health
Manatt Health integrates legal and consulting expertise to better serve the complex needs of clients across the healthcare system. Combining legal excellence, first-hand experience in shaping public policy, sophisticated strategy insight and deep analytic capabilities, we provide uniquely valuable professional services to the full range of health industry players. Our diverse team of more than 160 attorneys and consultants from Manatt, Phelps & Phillips, LLP, and its consulting subsidiary, Manatt Health, is passionate about helping our clients advance their business interests, fulfill their missions and lead healthcare into the future.

About the National Academy for State Health Policy
The National Academy for State Health Policy is a nonpartisan forum of policymakers throughout state governments, learning, leading and implementing innovative solutions to health policy challenges. To accomplish our mission we:

- Convene state leaders to solve problems and share solutions
- Conduct policy analyses and research
- Disseminate information on state policies and programs
- Provide technical assistance to states

The responsibility for health care and health care policy does not reside within a single state agency or department. At NASHP, we provide a unique forum for productive interchange across all lines of authority, including the executive and legislative branches.