Federal Administrative Pathways to Promote Access to Quality Methadone Treatment

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I have no conflicts to disclose.

I did work or consult in recent years for several federal government offices:
House Budget Committee, Office of Management & Budget, and Department of Justice.

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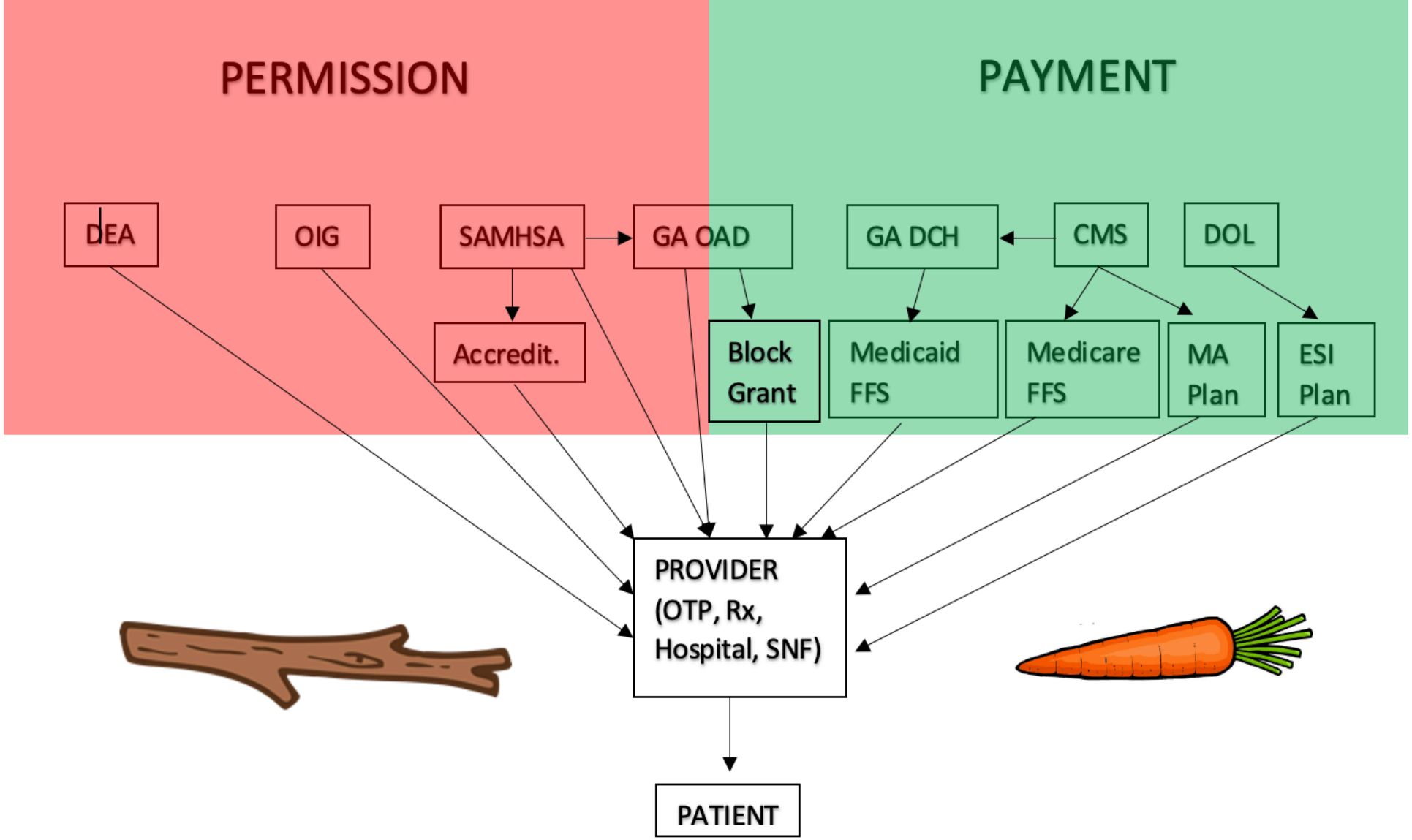
Synopsis

The National Academies of Science, Engineering, and Medicine commissioned this paper for *Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws – A Workshop*. It surveys pathways through which federal agencies could promote access to quality methadone treatment by utilizing existing legal authorities, without the need for federal or state legislation. It reviews existing analyses identifying specific pathways that federal agencies already have authority to utilize and points to promising areas in which further research may reveal additional flexibilities. Topic areas include the Substance Abuse and Mental Health Services Administration's (SAMHSA) standard-setting and Drug Enforcement Administration's (DEA) waiver authorities under the Controlled Substances Act; Health and Human Services Office of Inspector General (HHS OIG) authorities related to the antikickback statute; statutory and constitutional checks on state and opioid treatment program (OTP) restrictions; and payment authorities related to Medicare, Medicaid, and employer-sponsored insurance.

Roadmap

1. Permission
2. Payment
3. Regulatory process



Reform to scale = Permission + Payment
(sticks) (carrots)

1. Permission

- **Section 823(g) of CSA gives Secretary of HHS standard-setting authority, including power to change standards creating and governing OTPs. (Secretary delegated this power to SAMHSA.)**
- **Section 822(d) of CSA gives Attorney General power to "waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety." (AG delegated this power to DEA.)**

E.g., DEA promulgated mobile van permissions using waiver authority.

See generally Bridget C.E. Dooling & Laura Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Unsupervised Use of Opioid Treatment Medications*, 105 MINN. L. REV. HEADNOTES 74 (2021);

Corey S. Davis and Derek H. Carr, *Legal and policy changes urgently needed to increase access to opioid agonist therapy in the United States*, 73 INT. J. DRUG POL'Y 42-48 (2019).

2. Payment

- **Traditional Medicare.** Payment bundle needs formula revisions to maintain (or increase) OTP payments. 86 Fed. Reg. 66031 (Nov. 19, 2021).
- **Traditional Medicare.** Could develop model/code for reimbursement of non-OTP dispensation (Part D).
- **Medicare Advantage.** Utilization management a huge question mark. Prior authorization, copays, step therapy. Need data. CMS indicated in 2019 "considering strategies . . . to monitor." 84 Fed. Reg. at 62762 (Nov. 15, 2019). What is status of this?
- **Medicare Advantage.** Network adequacy checks omit methadone/OTP coverage. Include via guidance. CMS, *Medicare Advantage Network Adequacy Criteria Guidance* (Jan. 10, 2017).
- **Medicare Advantage.** ACA requires CMS to review and revise risk adjustment for mental health, SUD. Do so to to ensure maximum payment for SUD patients.

2. Payment

- **Medicaid (FFS and managed care).** CMS can pressure or encourage states to satisfy statutory requirement that reimbursement be "sufficient," though agency has struggled to enforce this provision. 42 U.S.C. 1396a(a)(30)(A).
- **Medicaid managed care.** Utilization management a black box, but managed care providers have incentive to impose unnecessary barriers on care. CMS could decide and implement mechanism to identify and address inappropriate barriers.
- **Medicaid waivers.** CMS can leverage fiscal flexibilities through 1115 to encourage states to promote access to methadone. *Cf.* IMD waivers, community engagement aka work requirements.

Source: Matthew B. Lawrence, *Parity is Not Enough! Mental Health, Managed Care, and Medicaid*, 48 J. L. Med. & Ethics 480 (2020).

2. Payment

- **Employer sponsored insurance.** Department of Labor 2022 parity report found that: "health plans and health insurance issuers are failing to deliver parity for mental health and substance-use disorder benefits to those they cover."
- E.g. DOL found large employer plan with 7600 beneficiaries unlawfully excluded methadone coverage altogether.
- DOL can leverage existing authorities to enforce but these are limited. Congress considering bolstering DOL parity enforcement authorities. *See* Alice Miranda Ollstein, *Mental Health Push in Congress Sparks Lobbying Frenzy*, Politico (Feb. 13, 2022).

Source: U.S. Depts of Labor, Health and Human Services, and Treasury, 2022 Mental Health Parity and Addiction Equity Report to Congress (Jan. 25, 2022).

3. Regulatory process

Question: Why did it take a viral pandemic for federal agencies to adopt take-home and telehealth flexibilities?

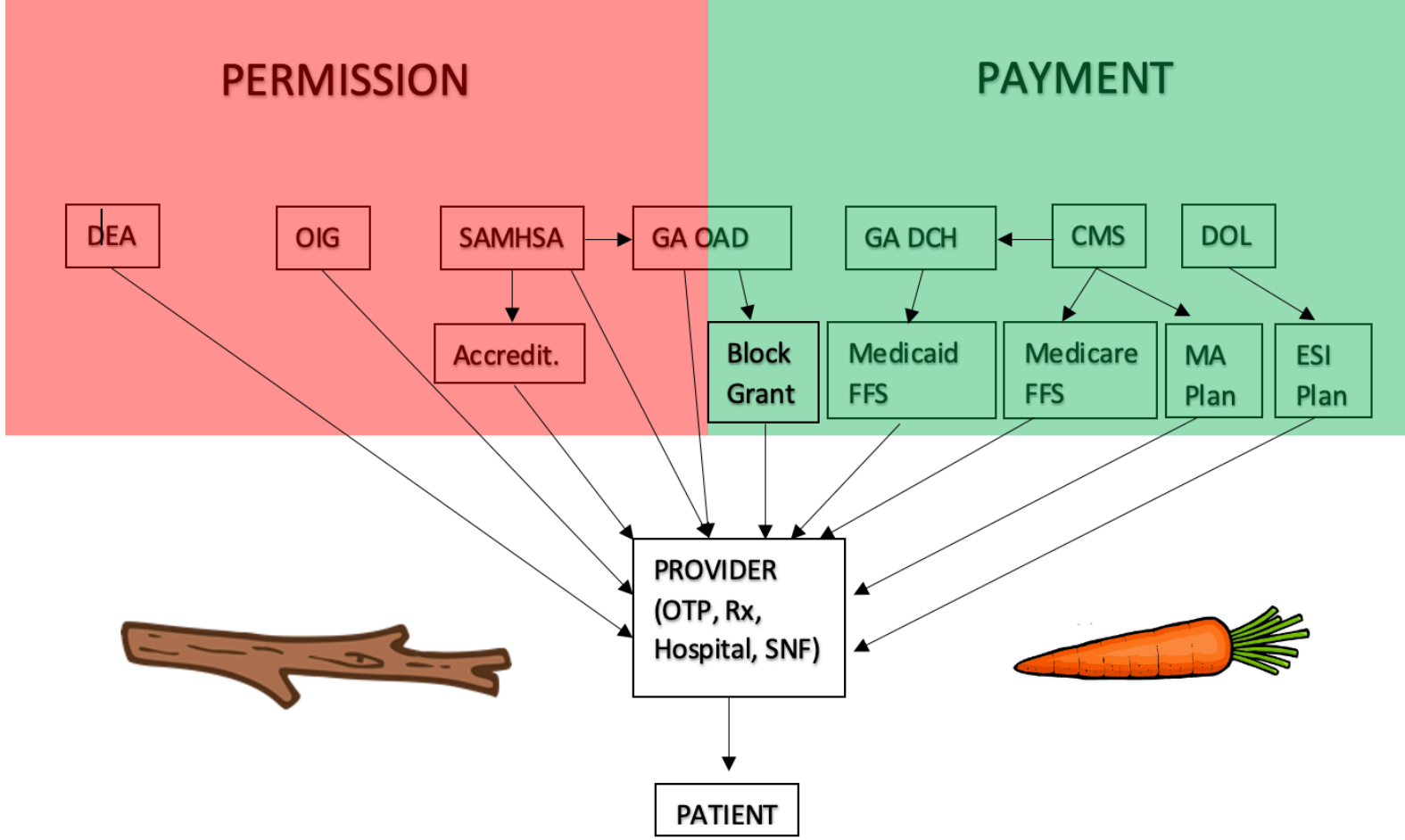
It was not for lack of authority.

One answer: "Ossification"

"Ossification" = High costs of regulatory change create strong bias for status quo.
E.g. Richard J. Pierce, *Rulemaking Ossification is Real*, GW Reg. Studies Center (March 19, 2014).

Contributors to ossification in methadone <u>regulatory structure</u>:

1. **Horizontal fragmentation (several federal regulators)**
2. **Vertical fragmentation (federal, state, local, institutional regulators)**
3. **Organized, expert industry constituents (OTPs)**
4. **Disempowered regulatory beneficiaries (patients, potential patients)**



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Barrier	Response	Comparator	Possible application
Horizontal fragmentation (several federal regulators)	**Energetic executive leadership through HHS, ONDCP, and/or WH with agenda-setting authority over entire federal apparatus**	--Cancer "moonshot" --Executive order on competition, 86 Fed. Reg. 36987 (July 14, 2021). --Affordable Care Act, Tri-agency rulemakings. *E.g.* 83 Fed. Reg. 57,592 (Nov. 15, 2018).	--Methadone "moonshot" --Executive order commanding agencies consider specific reg. changes. --Multi-agency rulemaking exercising ALL federal authorities, with one agency leading.
Horizontal fragmentation (several federal regulators)	**Simplify by pooling authorities**	--HHS OIG deputizes CMMI with safe harbor for payment models. 85 Fed. Reg. 77684 (Dec. 2, 2020).	--DEA deputizes CMMI by waiving all providers participating in payment model tests, or even nationwide payment model expansions.
Vertical fragmentation (federal, state, local)	**Use federal authorities to encourage state alignment**	--"Community engagement" (work requirement), IMD, reinsurance **waiver models**. *E.g.* SMD—18-002.	--CMS could issue guidance inviting states to apply for waivers to test, e.g., pharmaceutical dispensation. "Laboratories of democracy."
Disempowered regulatory beneficiaries	**Include perspective of people with lived experience receiving or being unable to access methadone treatment in agenda setting**	--APA section 553(e) rulemaking petition process. --Title VI complaint process, EPA Office of Civil Rights.	--Patients' groups could file petitions with DEA, SAMHSA to force public consideration. --Agencies could bolster, publicize process for investigation of complaints re: coverage barriers.

Thank you!

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