Why submit comments on draft regulations

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National Viral Hepatitis Roundtable

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Disclaimer

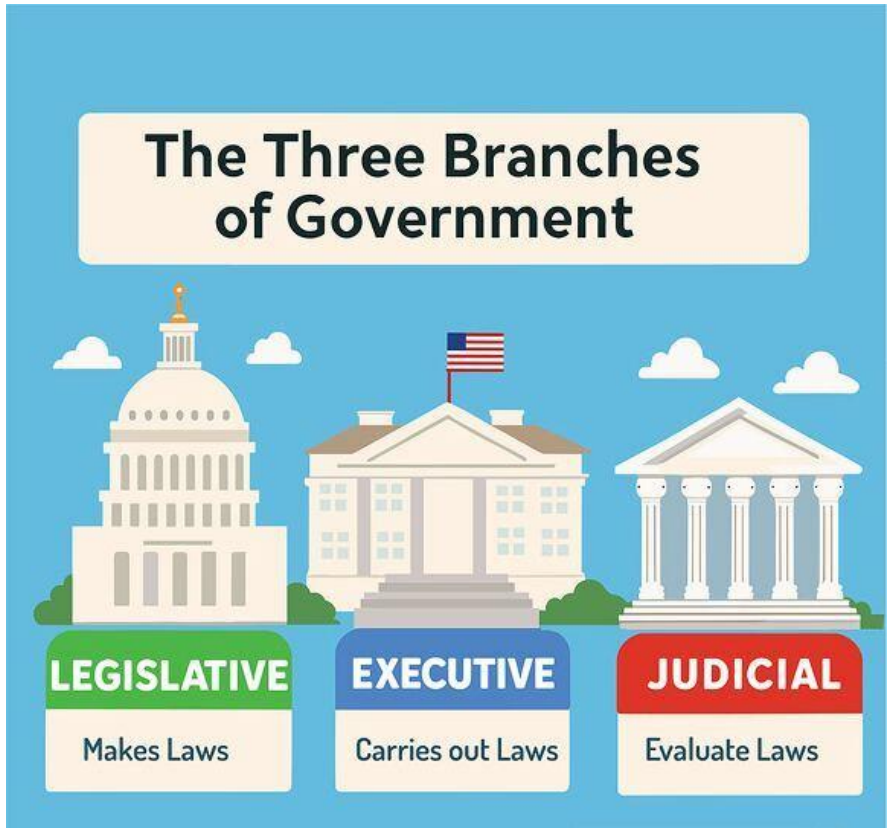
I am not a lawyer, and this presentation does not constitute legal advice. Opinions are my own and not necessarily those of NVHR. Please consult your in-house counsel for legal advice.

Agenda

01	What are regulations, again?
02	Why do they matter?
03	How can we influence them?
04	When has it made a difference?
05	Where do I start?

1. What are regulations again?

A regulation implements or enforces a law



Laws

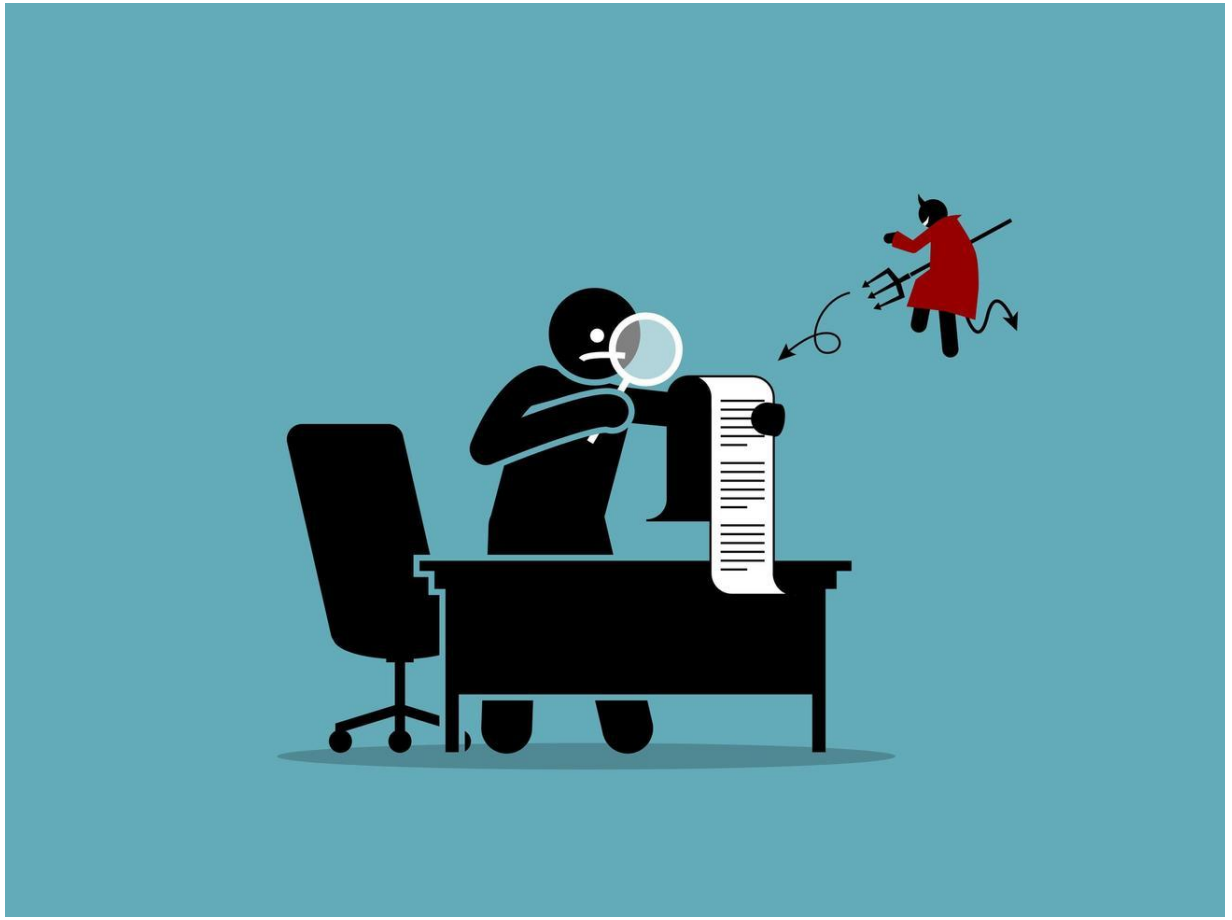
- Written/passed by Legislative
- Signed by the Executive
- May **allow** or **require** the Executive Branch to issue regs

Regulations

- Written by Executive agencies
- Set standards for enforcing and implementing specific law(s)
- Published in the Federal Register

2. Why do regulations matter?

Regulations have the force of law…for good or for bad



Example Law: Affordable Care Act, Section 1557, Prohibiting Discrimination in Healthcare

Regulation: 2021

- Executive Branch interpreted* ACA sex discrimination protections to include:
  - Gender identity
  - Sexual orientation

Regulation: 2025

- Executive Branch rescinded** this interpretation

* 86 FR 27984 (May 25, 2021)

** 90 FR 20393 (May 13, 2025)

3. How can we influence regulations (and other policies)?

Federal law requires allowing public input

5 U.S. Code § 553 - Rule making

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

2 CFR § 200.202 - Program planning and design

(b) Federal agencies should develop programs in consultation with communities benefiting from or impacted by the program.

Submit public comments at each step in the regulatory ("rulemaking") process!

1. **Before:** Advanced Notice of Proposed Rulemaking
   - Agencies evaluate the costs vs. benefits of issuing a new rule and post their evaluation in the Federal Register (federalregister.gov) for comment.
   - Public can comment at regulations.gov on whether to issue a new rule.
2. **During:** Notice of Proposed Rulemaking & Public Comment
   - After deciding to issue a rule, agencies post the text of a proposed rule in the Federal Register for a public comment period (often 60 days).
   - Public can comment at regulations.gov on the draft proposed rule.
3. **After:** Final Rule
   - Agencies must review all public comments and respond to them comments when issuing (or deciding to withdraw) their final rules.

Source: https://www.regulations.gov/learn


4. When has it made a difference?

Examples of when public comment made a difference in national or federal rulemaking

Proposed Policy or Rule	Before	After
U.S. Preventive Services Task Force, Hepatitis C Screening Recommendation, 2012*	"C" grade - Screening of minimal benefit. - Coverage not required.	"B" grade - Screening of moderate benefit. - Health plan coverage required.
Drug Enforcement Administration (DEA) and U.S. Department of Health and Human Services (HHS) Joint Notices of Proposed Rulemaking, 2023**	End COVID-19 era flexibilities allowing clinicians to prescribe controlled substances (including buprenorphine for treatment of opioid use disorder) without an in-person visit and via audio-only	After receiving 38,369 public comments, DEA and HHS extended the COVID-19 telehealth flexibilities for the fourth time, for another year, through December 31, 2026.
Office of Management and Budget, Regulation for Federal Financial Assistance, 2026	All federal discretionary grantmaking would be up to political appointees and could be terminated at any time.	TBD: As of July 12, 2026, OMB had received 278,884 public comments on the draft rule!!!

* USPSTF recommendations are not federal regulations, but because the ACA requires health plans to cover preventive services with an "A" or "B" rating, they affect the law's implementation. Edlin, 2012.

What if the Executive Branch ignores comments?

- Plaintiffs (people/organizations) suing the Executive Branch to oppose or overturn a draft or final rule can cite public comments
- Judges can cite public comments when considering plaintiff's arguments when they are suing for or against a proposed rule*
- Congress can reject and overturn regulations that it opposes** and may pay closer attention if a rule has widespread opposition

Sources:

* Network for Public Health Law

** Reginfo, OMB Office of Information and Regulatory Affairs


5. Where do I start?

Look out for public comment opportunities

- Subscribe to health policy updates (see Resources slide)
- Check social media (especially LinkedIn); many experts post there
- Individuals and groups often post analyses of public comments and sample talking points
  - Note: It is very important to use your own words when submitting public comments. The federal government may ignore duplicate comments.

How to analyze a proposed rule

- Review the rule
  - Read what other people whose opinions you trust have written about it
  - (Put the draft rule into AI and ask it for a summary—might be inaccurate)
  - If you enjoy diving into the weeds, copy the rule into a Word/google document or print it out and make your comments in the margins
- Think about how the rule would affect your work and the people you serve. If you have time, gather stories, data, cost info, etc.
- Draft bullet points summarizing whether you support or oppose the proposed rule and why, overall and as needed, by section

How to comment on a proposed rule

1. Go to federalregister.gov
2. Look for the rule by topic, title or Docket Number (e.g., CMS-2454-IFC)
3. Click on “Submit a Public Comment”
4. Fill out the form or upload a letter. If you write a letter, include the Docket#.
5. If commenting on a specific section, name that section (e.g., Section 435.557).

Sample comment #1 on Medicaid work rule

PUBLIC SUBMISSION

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Comment on CMS-2026-2047-0002

Posted by the **Centers for Medicare&Medicaid Services** on Jun 29, 2026

Docket / Document (CMS-2026-2047-0002) / Comment

Comment ID
CMS-2026-2047-0601

Tracking Number
mqs-pry8-2aqs

Comment Details | Submitter Info

Document Subtype
Public Comment

Received Date
Jun 24, 2026

Comment

I am asking the Centers for Medicare & Medicaid Services to protect people from losing care and reconsider the new Medicaid work requirement rules.

Medicaid is a lifeline for me, my family, and my community. It helps us access the care and services we need to live independently, stay connected to our communities, and support our families.

Requiring people to prove they are working 80 hours a month puts millions at risk of losing coverage, especially disabled people and older adults ages 50-64, who may find complex reporting systems harder to navigate because of their health. Requiring people with complex health conditions to prove that they are unable to work in order to keep their Medicaid without meeting 80 hours of work will hurt people with health conditions who need both health insurance and an income.

Access to care should not depend on someone's ability to navigate a complicated system. That's why I'm urging CMS to reject these rules and consider their impact on people and communities across the country.

Any change to Medicaid should invest more in care, not take away care from people who need it to survive.

Sample comment #2: Medicaid work rule

PUBLIC SUBMISSION

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Comment on CMS-2026-2047-0002

Posted by the **Centers for Medicare&Medicaid Services** on Jun 29, 2026

Docket / Document (CMS-2026-2047-0002) / Comment

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CMS-2026-2047-0211

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Received Date
Jun 21, 2026

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1

Comment

Community Engagement Requirement for Certain Individuals, CMS-2454-IFC
Docket ID: CMS-2026-2047
To the Centers for Medicare & Medicaid Services:
I support CMS's effort to implement the community-engagement requirement enacted by Congress while preserving the statutory exclusions and procedural protections that keep people from losing Medicaid coverage because their circumstances or health needs were not fully recognized. My comments focus on proposed 42 C.F.R. 435.554(c)(5)(ii), 435.557, 435.558(c), and 435.561.
I support the rule's requirement that state agencies use reliable information already available to them before asking a beneficiary for additional documentation. Section 435.557 appropriately recognizes claims, encounter data, case records, and information from other agencies as possible sources for identifying community engagement, exceptions, and exclusions. Also, the proposed outreach requirements in 435.561, including advance notice and use of at least two delivery methods. It's important because Medicaid beneficiaries may move frequently, have unstable access to mail or technology, or need information in a language other than English.
However, CMS should strengthen 435.554(c)(5)(ii), which requires each state to create and revise a list of diseases, diagnoses, disorders, or health conditions that may identify people who are medically frail or otherwise have special medical needs. The regulation requires the lists to be auditable, justifiable, and consistent with the rule, but it doesn't require that they be publicly available or that affected communities have an opportunity to provide input. I recommend that CMS require states to publish their lists and review them at least annually with input from behavioral health providers, disability advocates, health care social workers, and people with lived experience. The review should consider whether the list identifies conditions that can significantly affect a person's ability to meet the community-engagement requirement, including disabling mental disorders, substance use disorders, trauma-related conditions, and developmental disabilities.

Practice Run: Submit comments on the Medicaid Work Requirements, Interim Final Rule

- Review this analysis of the Interim Final Rule by the HIV and Hepatitis Policy Institute (or a similar organization)
- Draft comments on how this rule would affect people with viral hepatitis and other comorbidities using your own language
- Submit your comments by July 31, 2026 at https://www.regulations.gov/commenton/CMS-2026-2047-0002
  - Find out if you can comment on behalf of your organization.
  - If not, you can comment anonymously or as an individual and include a note that says something like “These opinions letter are my own and do not necessarily represent those of my employer or its funders.”

Resources

- Health Care in Motion
- HIV and Hepatitis Policy Institute
- KFF “What the Health?”
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- National Association of City and County Health Officials (NACCHO)
- Network for Public Health Law
- Public Health Awakened

Contact Information

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Book time with Ray