RHC Legislative and Regulatory Update

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Agenda

Legislative

- 2024 Congressional Activity
- NARHC Legislative Priorities
  - 118th Congress
  - 119th Congress

Regulatory

- CMS Proposed Rules Calendar Year 2025
  - Changes to Required Labs & Productivity Standards
  - Care Management Billing Changes
  - Proposals to clarify "primarily engaged in primary care"
- Other New Regulations
  - FTC Non-Compete
  - HHS Nondiscrimination
- **Plus, how to be involved in it all!**

NARHC Overview

"To educate and advocate for Rural Health Clinics, enhancing their ability to deliver cost-effective, quality health care to patients in rural, underserved communities."

Education:

NARHC ACADEMY
EDUCATING RHC PROFESSIONALS ACROSS THE US

Technical Assistance Webinars

- Mobile Units and Your RHC – Is this a good fit?
- RHC Billing 101

Conferences

Legislative & Regulatory Advocacy:

NARHC Advocacy Letters and Comments

NARHC often communicates with Congress and the Administration on issues of importance to the Rural Health Clinic community. The following is an archive of official communications we have sent advocating on behalf of the Rural Health Clinic Program. We have also included some communications and letters that NARHC has signed but were not authored by NARHC.

June 26, 2024 - Statement for the Record CMMI Hearing

June 18, 2024 - Statement for the Record 340B Oversight Hearing

May 30, 2024 - Joint Letter to Energy and Commerce Leadership

May 30, 2024 - Statement for the Record, Senate Finance Committee Rural Health Hearing

May 29, 2024 - CMS Medicare Advantage Data Request for Information Response

May 28, 2024 - RFI Response - Rural Definition Proposed Changes - FORHP Grants

April 25, 2024 - MedPAC April Public Meeting Statement for the Record

March 28, 2024 - CPT Category II ~ Letter to the Administrator

Join the fight for rural health and make your voice heard here!

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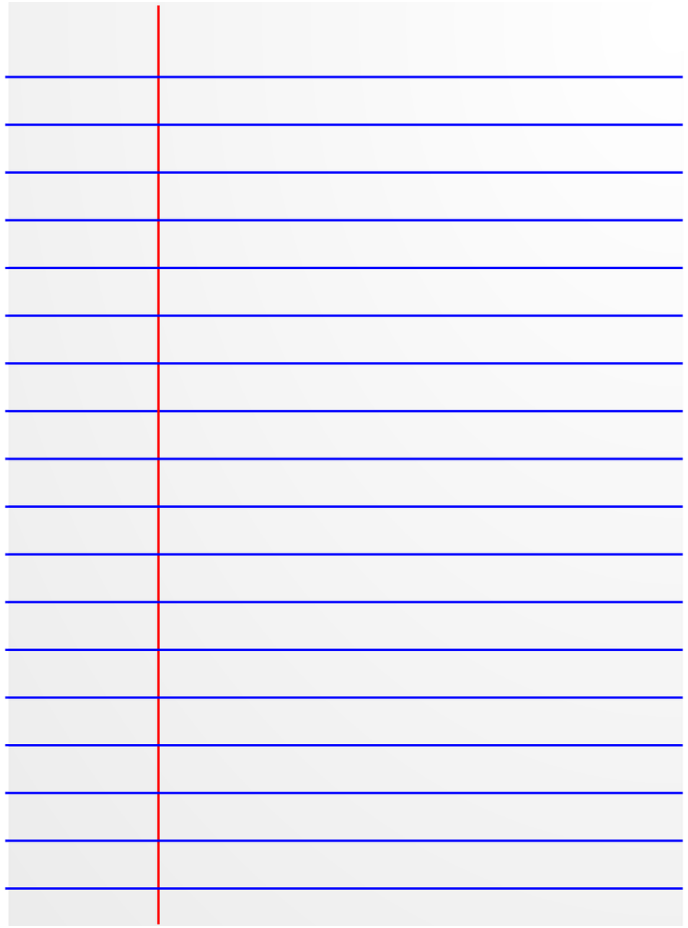
Activity of the 118th Congress (2023-2024)



- ~80 bills passed (17,000+ introduced)
  - Of these, 7 renamed post offices and 5 renamed VA clinics
- Nearly 300 less bills passed than in the previous Congress!

In 2024 Congress Must…

- Campaign! ✓
- Fund the government
  - FY25 begins October 1, 2024
  - Typically, funding bills serve as the opportunity to get smaller pieces of legislation passed
  - Continuing Resolutions (CRs) are short term funding bills that typically extend current funding levels – Congress passed one through December 20th
- Congress must extend Medicare coverage of telehealth if it is to continue beyond 2024 (which we expect) ✗

So, what can we do?

NARHC Immediate Priorities-118th Congress

Telehealth

Current Medicare Telehealth Coverage - RHCs

Medical Telehealth

- RHCs can serve as telehealth distant site providers through **December 31, 2024** (at least)
- Paid $96.87 for all services on Medicare's telehealth list (200+ codes)
  - Including many via audio-only
  - Do not count as encounters; costs and visits carved out of cost report – Billed as G2025

Mental Health Telehealth

- **Permanent** coverage in the RHC setting, reimbursed at All-Inclusive Rate, counted as a visit
- In-person requirements are waived until January 1, 2025
  - Occasional requirement (6 months prior to furnishing telehealth; at least once per year)
- CPT codes billable with 0900 revenue code

NARHC Policy Position

- Three primary concerns with current G2025 system:
  - Limited data can be gathered by billing 1 single code for a variety of services
  - The payment rate disincentivizes investment in telehealth technology
  - Entirely new billing and cost reporting rules increase administrative burden

- What we want:
  - Normal coding, cost reporting, billing, reimbursement
  - **Pay telehealth encounters through All-Inclusive Rate system**

Telehealth Legislative Outlook

- Without Congressional action, current Medicare medical telehealth flexibilities will expire on December 31, 2024
- Telehealth has significant bipartisan and widespread industry support
- Several pieces of legislation have been introduced this Congress that achieve our telehealth priorities
  - Section 105 of **S. 2016/HR 4189 -** The CONNECT for Health Act of 2023;
  - Section 2 of **H.R. 5611 -** The HEALTH Act of 2023;
  - Section 113 of **H.R. 833** - Save America's Rural Hospitals Act
  - Section 2 of **H.R.7623/S.3967** – Telehealth Modernization Act

Latest Congressional Activity

- In addition to introducing telehealth bills, relevant committees have been hosting telehealth hearings and markups.

- The House Ways & Means Committee marked up a piece of telehealth legislation that simply extends current telehealth policy (including G2025) for 2 years.

- The House Energy & Commerce Subcommittee on Health marked up a piece of telehealth legislation that **fixes** G2025 policy in a 2-year extension!

- Senate Telehealth Working Group sent a letter in support of payment parity for RHCs/FQHCs

NARHC Priorities 119th Congress

- Continue to increase awareness of the RHC program
  - Ensure that every Member of Congress knows about the 5,500+ RHCs and the 38.7 million patients they serve

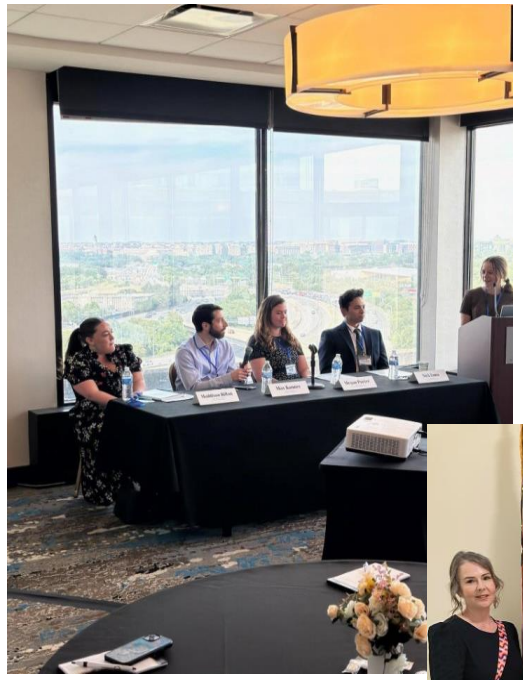
- Pass elements of the **RHC Burden Reduction Act** depending on regulatory relief issued by CMS

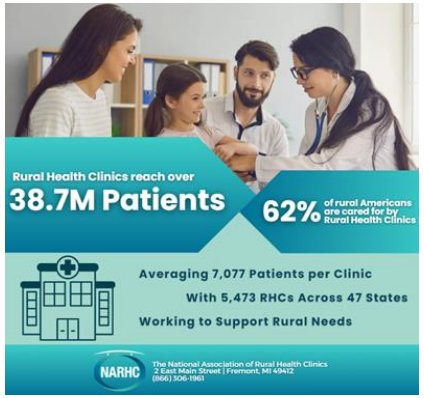
- Further engage RHCs in grant opportunities
  - RHC Behavioral Health Initiative

- Medicare Advantage reforms
  - Widespread interest in prior authorization reform
  - RHC and CAH payment reforms / reimbursement protections
  - MedPAC report expected June 2025
  - **We cannot let MA diminish the rural safety-net**

How to be involved in RHC Advocacy

- Voter Voice Tool
  - https://www.votervoice.net/NARHC/Home
- NARHC Annual Policy Survey
- NARHC Fellowship
- NARHC Policy Summit



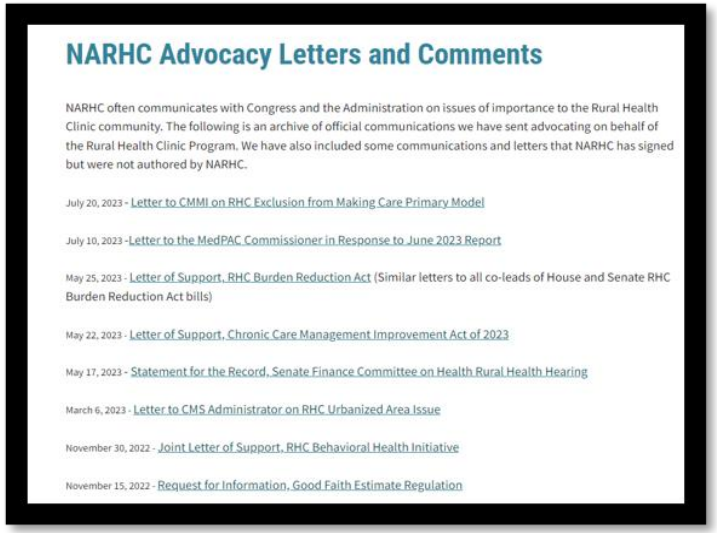


2025 Proposed Rules: Medicare Physician Fee Schedule (MPFS) Other New Regulations

CMS Rulemaking Process

July – MPFS and OPPS Proposed Rules Released

- What's in the proposed rules for RHCs webinar - August 15



NARHC Advocacy Letters and Comments

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July 20, 2023 - Letter to CMMI on RHC Exclusion from Making Care Primary Model

July 10, 2023 - Letter to the MedPAC Commissioner in Response to June 2023 Report

May 25, 2023 - Letter of Support, RHC Burden Reduction Act (Similar letters to all co-leads of House and Senate RHC Burden Reduction Act bills)

May 22, 2023 - Letter of Support, Chronic Care Management Improvement Act of 2023

May 17, 2023 - Statement for the Record, Senate Finance Committee on Health Rural Health Hearing

March 6, 2023 - Letter to CMS Administrator on RHC Urbanized Area Issue

November 30, 2022 - Joint Letter of Support, RHC Behavioral Health Initiative

November 15, 2022 - Request for Information, Good Faith Estimate Regulation

September – Comments Due

November – Final Rules Released

January – Provisions go into effect & it begins again!

Medicare Vaccine Reimbursement Changes

- *Currently*:
  - RHC statute requires that Medicare preventative vaccines (pneumococcal, flu, COVID-19) and their administration be reimbursed at 100% of reasonable costs
  - The hepatitis B vaccine is currently reimbursed as part of the RHC All-Inclusive Rate (co-insurance/deductible waived)
- *Proposed*:
  - CMS is proposing to allow RHCs to bill for the administration of pneumococcal, flu, COVID-19, **and** hepatitis B vaccines at time of service
    - Would pay 95% of Average Wholesale Price for vaccines and the admin would be reimbursed according to the Part B vaccine fee schedule, adjusted for locality
    - To reach 100% of reasonable costs, however, RHCs will still reconcile with CMS via the cost report

Medicare Vaccine Reimbursement Changes

- *NEW At-Home Vaccine Administration Reimbursement*
  - RHC providers can bill HCPCS code M0201 when flu, COVID-19, pneumo, or hep B vaccines are administered in the patient's home
  - Approximately $38 in additional reimbursement

- *NARHC Questions / Comments*:
  - Billing at time of service will help with cash flow issues
    - However, it will not address the dynamic that causes Medicare to reimburse below costs for vaccine administration in some cases. When vaccine costs for the Medicare patients are disproportionately above the overall share of Medicare costs, RHCs will still receive less than their actual costs for vaccines.
    - Therefore, NARHC commented in support of this proposed change while also urging CMS to address these issues with the existing methodology
- ***July 1, 2025 effective date***

Elimination of Productivity Standards

- *Currently*:
  - RHC productivity standards are 4,200 visits per full-time equivalent (FTE) physician and 2,100 visits per FTE nurse practitioner, PA, and certified nurse midwife
  - Since all RHCs are now subject to some sort of upper payment limit (either the clinic specific cap for grandfathered RHCs or the national statutory cap for new and independent RHCs), the productivity standards have been less important

- *NARHC Questions / Comments*:
  - NARHC has advocated for a revision to the productivity standards and commented in support of this proposal

Medicare Care Management Reforms and New Opportunities

- *Currently*:
  - Since 2016, RHCs have been able to bill for care management services through a consolidated care management code: G0511 (~$72 reimbursement)
    - Each year, CMS added new services billable under the G0511 code
      - This consolidated code is used when RHCs want to bill for Chronic Care Management (CCM), Remote Physiologic Monitoring (RPM), General Behavioral Health Integration (GBHI), Community Health Integration (CHI), and more!
    - Beginning in 2024, the G0511 code was finally billable more than once per patient per month

  - The system was becoming a bit unwieldy, and there seemed to be variation in how MACs were operationalizing it
    - It was also impossible to tell which specific care management services were actually being performed and billed

Medicare Care Management Reforms and New Opportunities

- *Proposed*:
  - Allowing RHCs consolidated to bill the **individual CPT codes** on a UB-04 instead of G0511

Physician Fee Schedule Code	2024 Payment Rate	Short Descriptor
98975	$19.97	Rem ther mntr 1st setup&edu
98976	$47.27	Rem ther mntr dev sply resp
98977	$47.27	Rem ther mntr dv sply mscskl
98980	$50.60	Rem ther mntr 1st 20 min
98981	$39.95	Rem ther mntr ea addl 20 min
99091	$53.59	Collj & interpj data ea 30 d
99424	$82.55	Prin care mgmt phys 1st 30
99425	$59.92	Prin care mgmt phys ea addl
99426	$61.91	Prin care mgmt staff 1st 30
99427	$47.27	Prin care mgmt staff ea addl
99437	$59.58	Chrnc care mgmt phys ea addl
99439	$47.93	Chrnc care mgmt staf ea addl
99454	$47.27	Rem mntr physiol param dev
99457	$48.93	Rem physiol mntr 1st 20 min
99458	$39.28	Rem physiol mntr ea addl 20

Physician Fee Schedule Code	2024 Payment Rate	Short Descriptor
99474	$16.64	Self-meas bp 2 readg bid 30d
99484	$54.92	Care mgmt svc bhvl hlth cond
99487	$134.15	Cplx chrnc care 1st 60 min
99489	$72.23	Cplx chrnc care ea addl 30
99490	$62.58	Chrnc care mgmt staff 1st 20
99491	$84.55	Chrnc care mgmt phys 1st 30
G0019	$80.56	Comm hlth intg svs sdoh 60 mn
G0022	$50.26	Comm hlth intg svs add 30 m
G0023	$80.56	Pin srv 60 min pr m
G0024	$50.26	Pin srv add 30 min pr m
G0140	$80.56	Nav srv peer sup 60 min pr m
G0146	$50.26	Nav srv peer sup add 30 pr m
G0323	$54.92	Care manage beh svs 20mins
G3002	$82.55	Chronic pain mgmt 30 mins
G3003	$30.29	Chronic pain mgmt addl 15m

Medicare Care Management Reforms and New Opportunities

- *NARHC Questions / Comments*:
  - We appreciate CMS recognizing our concerns with the increasingly complex consolidated billing structure and supported this proposed change
  - Pros:
    - RHCs should now be included in new care management style opportunities at the same time as their fee-for-service peers
    - RHCs can bill for add-on/time-based codes
    - Less complicated billing structure
  - Potential Cons:
    - If your RHC **only** did 20 min of Chronic Care Management (CCM) per month, your reimbursement under G0511 methodology would be ~$72. Billing that FFS will reimburse ~$62.

Advanced Primary Care Management (APCM)

- Alternative, bundled way to provide care management
- Based on levels / number of chronic conditions instead of time
  - Level 1 – zero to one chronic condition – estimated reimbursement $10
  - Level 2 – two chronic conditions – estimated reimbursement $50
  - Level 3 – multiple chronic conditions **and** dual eligible – estimated reimbursement $110

Advanced Primary Care Management (APCM) Elements

- Patient consent
- Initiation of APCM during qualifying visit
- 24/7 access to a provider/care team
- Continuity of care; patient can schedule routine appts.
- Offer care through alternative modalities (home visits, extended hours)
- Comprehensive Care Management
- Electronic, patient centered care plan
- Coordinated transitions in care and ongoing communication amongst care teams
- Ability to communicate with care team via non-face-to-face methods other than telephone
- Population data analysis
- Risk stratification of patients to determine high-risk patients
- Performance measurement

Lab Requirements Changes

- *Proposed:*
  - CMS is proposing to remove hemoglobin and hematocrit (H&H) from the list of required labs
  - CMS is also proposing to update "primary culturing for transmittal to a certified laboratory" to "collection of patient specimens for transmittal to a certified laboratory for culturing"
  - In addition to supporting this, NARHC commented in support of removing the stool specimen requirement

Primary Care versus Specialty Services

- *Currently*:
  - RHC statute and regulation stipulates that RHCs must be primarily engaged in "providing **outpatient** services"
  - However, CMS State Operations Manual Appendix G (guidance) explains that "RHCs may **not** be primarily engaged in **specialized** services"

  - NARHC has pointed out this significant discrepancy for several years, however RHCs continue to be surveyed to the requirement that more than 50% of their hours must be the provision of **primary** care services

Primary Care versus Specialty Services

- *Proposed*:
  - CMS would add the following to the 491.9(2) **regulation**:
    - (i) The clinic or center must provide primary care services.

  - CMS states "we expect RHCs and FQHCs to offer a range of primary health care services to ensure that patients receive the necessary care at the earliest possible point of contact."

- *NARHC Comments*:
  - While CMS is technically *adding* something to the regulation, this is a *decrease* in the restrictive nature of the previously limiting threshold on specialty care to allow for greater flexibility for each individual RHC
  - Now, instead of being surveyed to the '50% of operating hours must be primary care' standard, RHCs will be surveyed to just providing 'some' primary care services

Mental Health Services

- *Currently*:
  - RHC statute reads that a Rural Health Clinic is "only a facility which... (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases."
  - This has been interpreted to mean that RHCs can only provide up to 49% of their services as behavioral health services
    - However, there is little to no guidance on *how* that 49% should be determined – Diagnosis codes? Types of providers? Services provided? Other?

- NARHC has been advocating to **Congress** to remove the specific section of the statute through a provision in the RHC Burden Reduction Act and simultaneously advocating to **CMS** to provide additional guidance on this outdated and arbitrary language.

Mental Health Services

- *NARHC Questions / Comments*:
  - We believe that CMS is risking additional unintended consequences by seeking to define "mental diseases"
  - Instead, we encouraged CMS to define "a **facility** which is primarily for the care and treatment of mental diseases"

- ***RHC statute reads that a Rural Health Clinic is "only a facility which... (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases."***
  - CMS defines a rehabilitation agency as: "[a]n agency that provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel."
  - However, they're seeking then to define *mental diseases* instead of
- **NARHC believes that CMS should define a *facility which is primarily for the care and treatment of mental diseases* instead of *mental diseases***
  - This way, CMS could explicitly say that facilities such as: Certified Community Behavioral Health Clinics (CCBHCs), Community Mental Health Centers (CMHCs), Opioid Treatment Programs (OTPs), and others could not be dually certified as an RHC. We agree that this is in alignment with the RHC statute.
    - However, if it is not one of those facilities, we do not find it necessary for CMS to issue additional restrictions on the type or amount of behavioral health services done in the RHC.

Federal Trade Commission Noncompete Ban

- The Federal Trade Commission (FTC) finalized a rule in April 2024 banning all existing (except for senior executives) and new noncompete agreements beginning September 4, 2024
- On August 20th, a federal judge blocked the rule, citing a lack of authority of the FTC
- **The ban is on hold and not in effect**
- Will likely eventually reach the Supreme Court

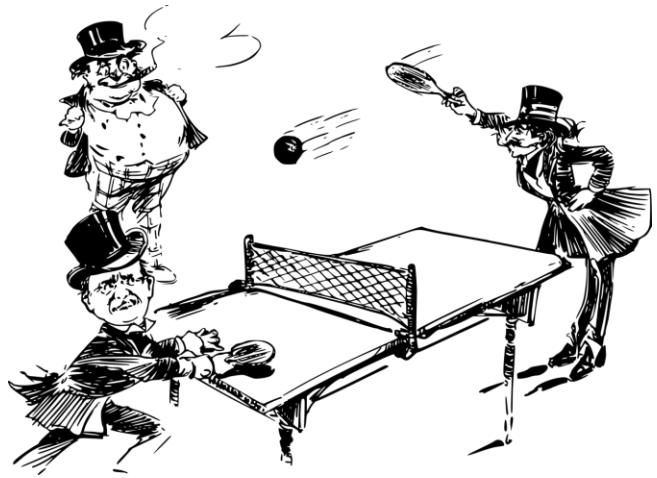
Regulatory Updates with RHC Impacts

HHS Nondiscrimination Rule

- When the Affordable Care Act (ACA) was signed into law in 2010, it contained a non-discrimination provision, Section 1557.
- Section 1557 "*prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in specified health programs or activities, including those that receive Federal financial assistance.*"
  - Federal financial assistance includes providers who receive reimbursement from Medicare/Medicaid/CHIP/ACA Marketplace Plans
- The law directed the Secretary of HHS to promulgate regulations to implement this section.
- July 15 NARHC Webinar

Regulatory History

- Regulations were first implemented by the Obama Administration in 2016, revised by the Trump Administration in 2020, and revised in 2024 by the Biden Administration.



On the basis of sex

- This regulation goes beyond past protections by extending "on the basis of sex" to include *sexual orientation, gender identity, sex characteristics, pregnancy or related conditions, and sex stereotypes*, consistent with the U.S. Supreme Court's decision in *Bostock v. Clayton County*

- HHS / Office of Civil Rights FAQs

Religious Freedom / Conscience Exemptions

15. Does the final rule include a religious freedom and conscience exemption?

Yes. The final rule reiterates that a recipient may rely on applicable Federal protections for religious freedom and conscience, and a particular application of a provision(s) of this final rule is not required when such protections apply. It also includes an administrative process for recipients to seek an assurance of exemption in writing from the application of a provision of Section 1557 under existing Federal religious freedom and conscience laws. The recipient will receive a temporary exemption while OCR decides the request. If the request is denied, the recipient can file an administrative appeal of that decision with HHS. OCR enforces a range of civil rights and conscience and religious freedom statutes and takes seriously the responsibility to effectively enforce each one. The final rule does not change or displace the rights already afforded under those statutes.

Required Coverage / Provision of Treatment

16. Does the final rule require the coverage or provision of treatment (e.g., hormone therapy, surgery, etc.) for children and/or adults with gender dysphoria if prescribed by a doctor?

The rule does not require a specific standard of care or course of treatment for any individual, minor or adult. Providers do not have an affirmative obligation to offer any health care, including gender-affirming care, that they do not think is clinically appropriate or if religious freedom and conscience protections apply. HHS has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual.

The final rule does not require those covered, including state Medicaid agencies, to cover a particular health service for the treatment of gender dysphoria for any individual, minor or adult. Rather, it prohibits health insurance issuers, state Medicaid agencies, and other covered entities from excluding categories of services in a discriminatory way. Coverage must be provided in a neutral and nondiscriminatory manner.

Section 1557 Lawsuits

- Nearly half of states as well as many legal groups, conservative medical associates, and individual facilities have all filed lawsuits to block this rule given the expanded interpretation of "on the basis of sex"

Status of Legal Challenges

- In early July, a U.S. Southern District Court Judge from MS blocked enactment of the rule for all states "to the extent that the final rule provides that 'sex' discrimination encompasses gender identity."
  - Other components of the 1557 final rule still apply

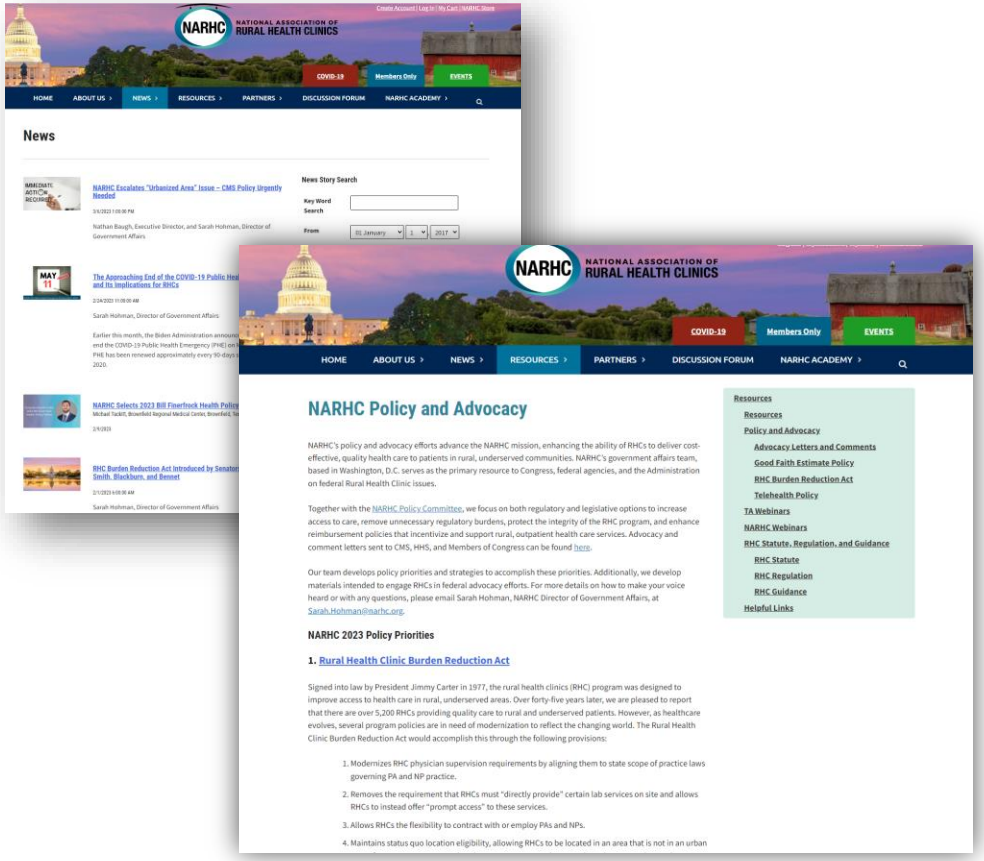
- Except for in Montana and Texas, where a Fifth Circuit Court of Appeals blocked the entirety of the rule for those two states in a separate case

While the full rule is broadly applicable to the healthcare industry, the following sections are the most immediate and relevant sections of the rule for Rural Health Clinics.

Section 1557 Requirement and Description	Covered entities must comply by:
§ 92.7 Section 1557 Coordinator	November 2, 2024
§ 92.10 Notice of Nondiscrimination ~ Longer notice required in English explaining Nondiscrimination rules to patients	November 2, 2024
§ 92.210 Nondiscrimination via Patient Care Decision Support Tools	May 1, 2025
§ 92.211 Nondiscrimination via Telehealth	May 1, 2025
§ 92.8 Policies and Procedures	July 5, 2025
§ 92.9 Training	After the creation of a covered entities P&P and no later than July 5, 2025
§ 92.11 Notice of Availability ~ Shorter notice in English and top 15 foreign languages explaining the availability of translation and auxiliary aid services free of charge	July 5, 2025

Stay “In the Know” on RHC Issues

- NARHC.org
  - Email Listserv
  - Discussion Forum
  - News Tab
  - Resources Tab
    - TA Webinars
    - Policy and Advocacy
- State rural health organizations & offices of rural health
- Federal Office of Rural Health Policy (FORHP) Weekly Updates
- RHIhub
- CMS RHC Center



NARHC Community Forum

Your resource to engage in discussions about all things Rural Health Clinics. The NARHC Community Forum serves as a valuable resource to ask questions, network with other professionals, share knowledge, and stay informed!

Scan to join!

How to join:

- Access the registration form through this QR code!
- Sign up to create an account & verify email
- Build your Community profile
- Access the community and start interacting!

Questions? Contact us at Academy@NARHC.org

Questions?

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