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The Omnibus Burden Reduction (Conditions of Participation) Final Rule for RHCs

Hour 2 of the RHC Update Seminar – January 16, 2020

H B S

Healthcare Business Specialists

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Experienced Knowledge

Agenda

Rural Health Clinics Modernization Act

The Omnibus Burden Reduction (Conditions of Participation) Final Rule

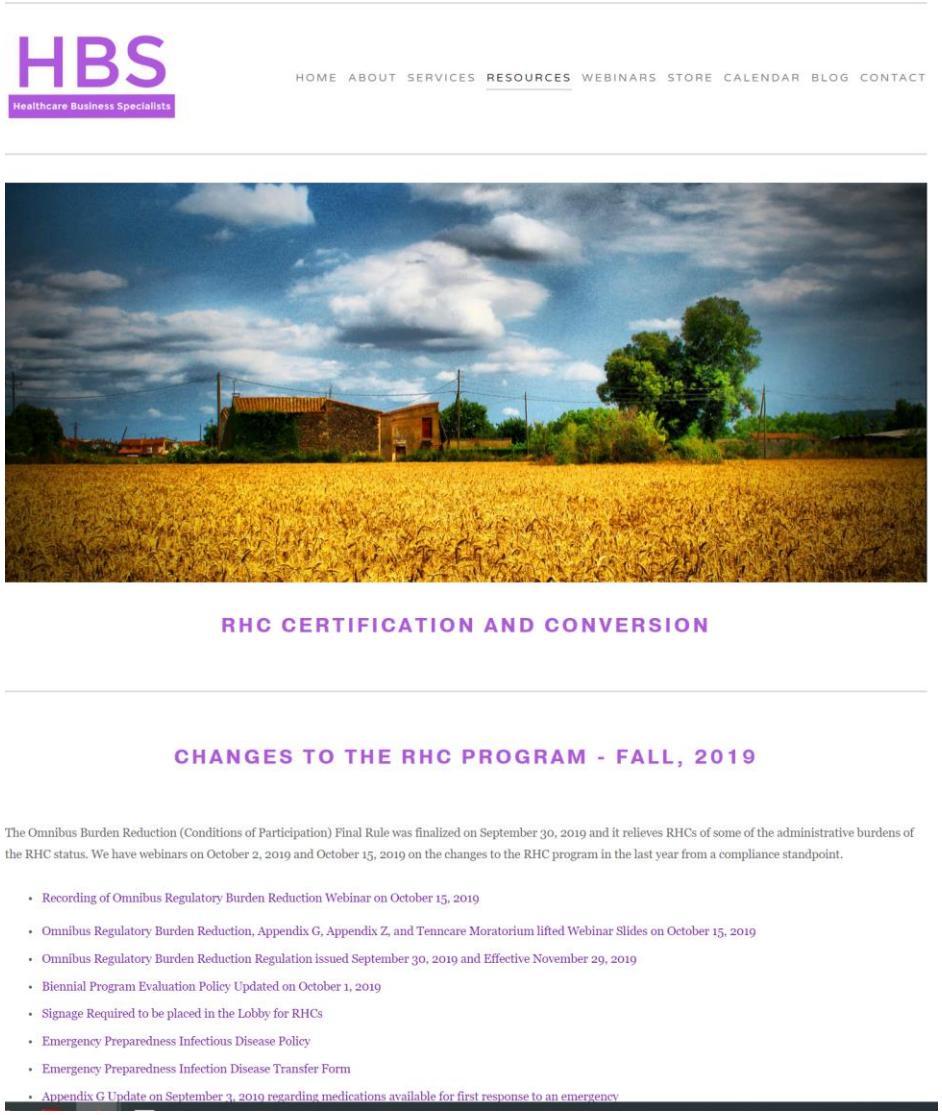
Appendix G Update – Emergency Kit Contents

Appendix Z Update – Infectious Diseases

Required Signage in the Lobby

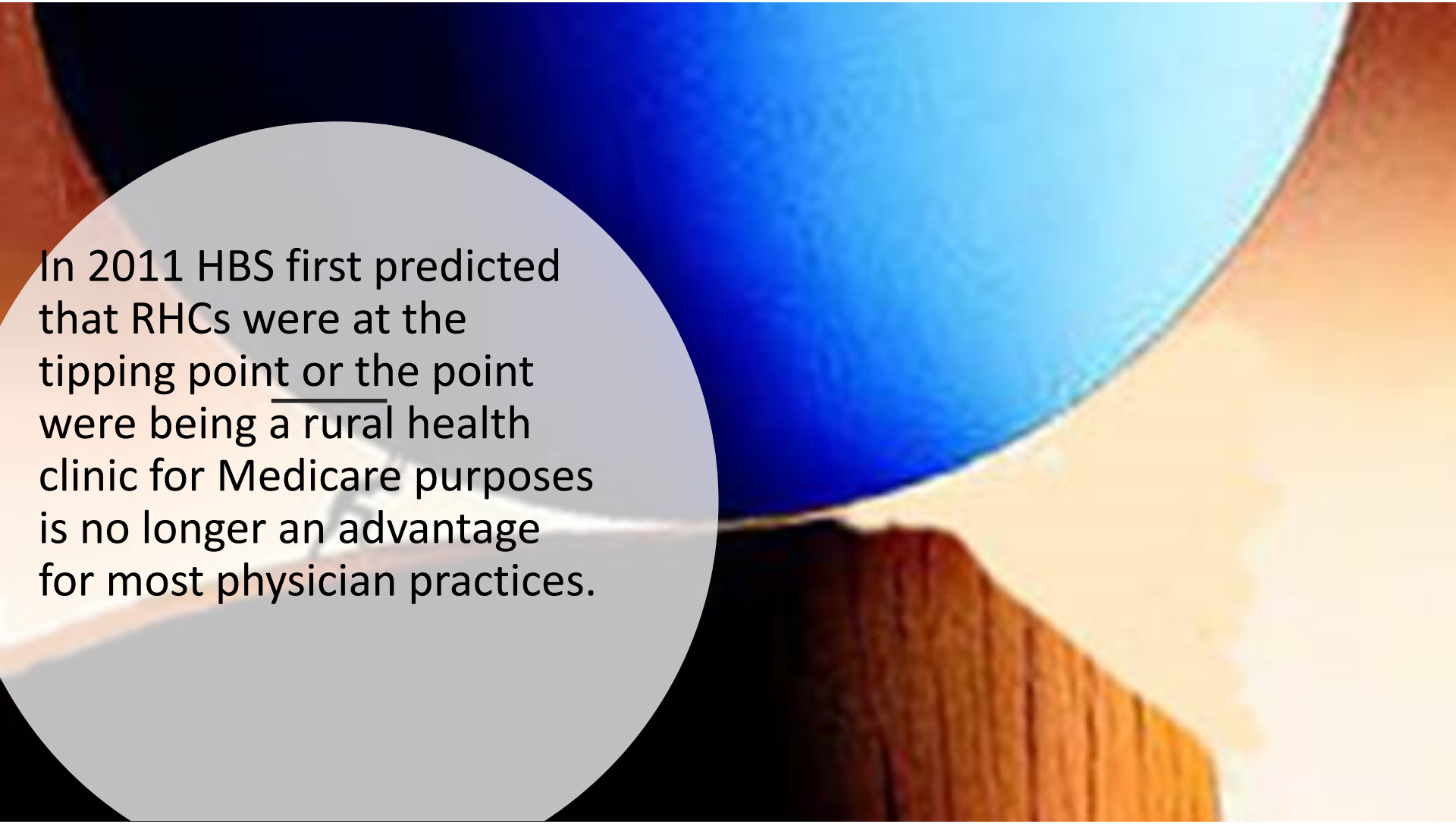
Questions

Where to find Materials from this hour in addition to what is on the Google Doc



http://www.ruralhealthclinic.com/certification-materials

S. 1037 - Rural Health Clinics Modernization Act


In 2011 HBS first predicted that RHCs were at the tipping point or the point were being a rural health clinic for Medicare purposes is no longer an advantage for most physician practices.

Since 2012, **700** RHCs have closed **or** transitioned from "Independent" to "Provider-based"

388 RHCs have closed since 2012!

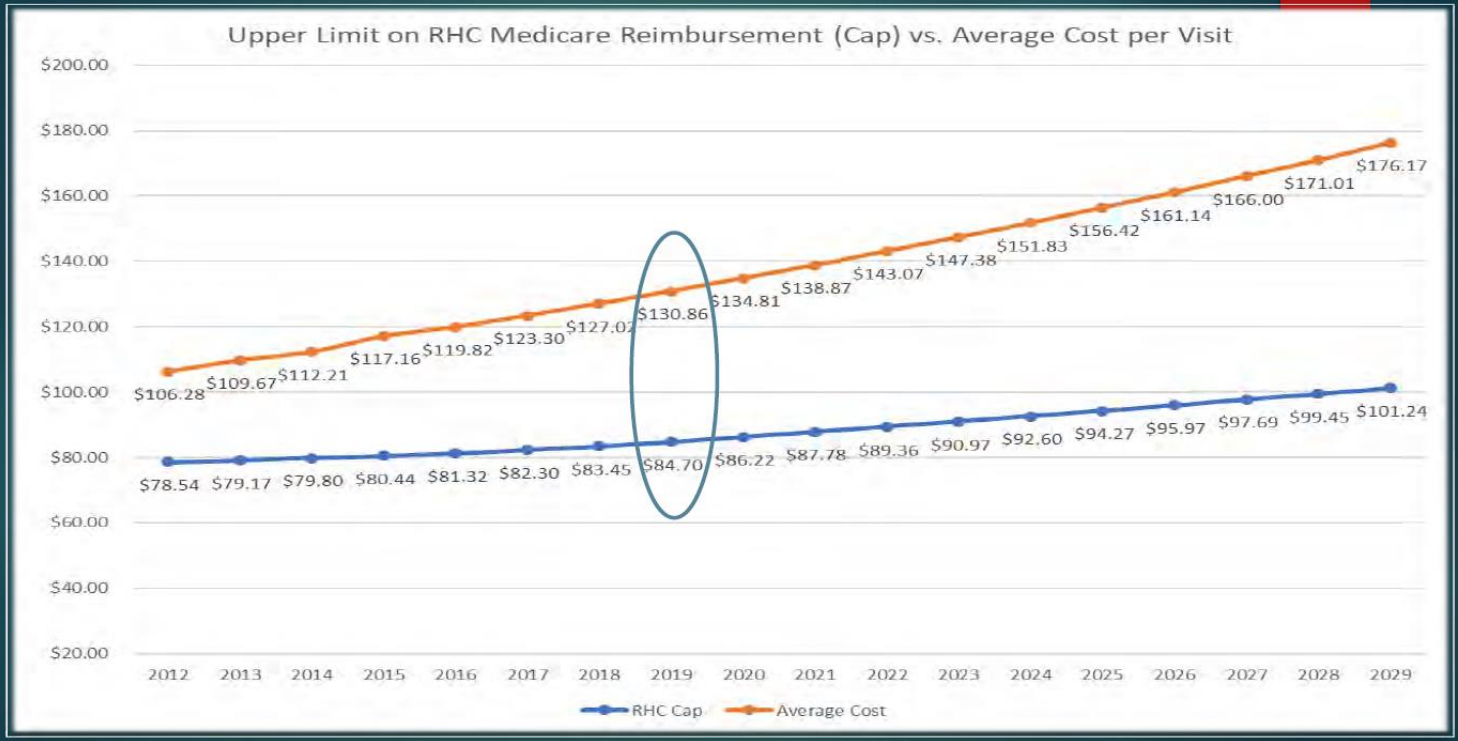
64% were Independent RHCs

36% were provider-based RHCs

312 Independent RHC's have converted to provider-based RHC (small hospital)

2012 – 2018 Top 10 states – RHC Closures

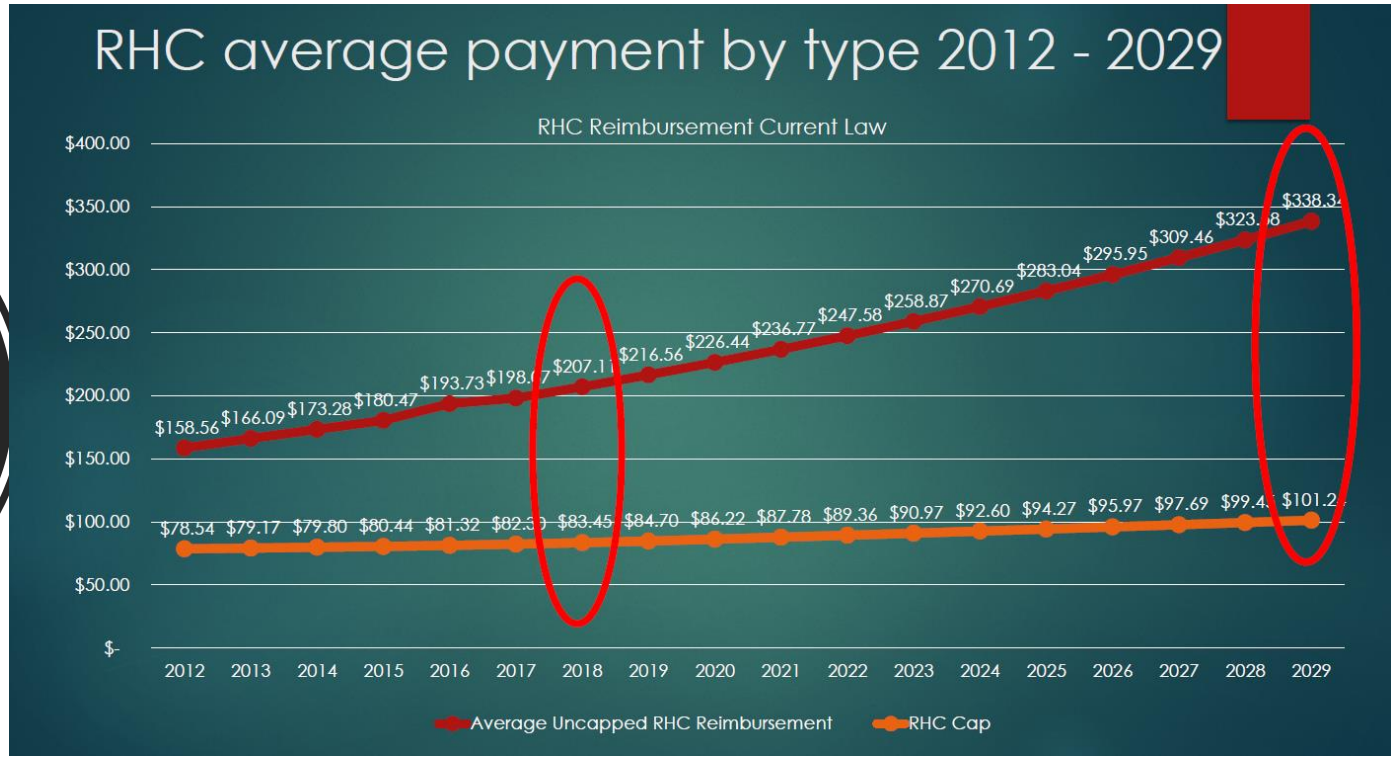
State	#RHC Close	State Rank
MO	44	1
TX	38	2
MS	32	3
FL	24	4
CA	22	5
SC	19	6
MI	18	7
NC	15	8
TN	15	8
IL	15	8


Upper Limit on RHC Medicare Reimbursement (Cap) vs. Average Cost per Visit
$200.00
$180.00
$160.00
$140.00
$120.00
$100.00
$80.00
$60.00
$40.00
$20.00
$106.28
$109.67
$112.21
$117.16
$119.82
$123.30
$127.02
$130.86
$134.81
$138.87
$143.07
$147.38
$151.83
$156.42
$161.14
$166.00
$171.01
$176.17
$78.54
$79.17
$79.80
$80.44
$81.32
$82.30
$83.45
$84.70
$86.22
$87.78
$89.36
$90.97
$92.60
$94.27
$95.97
$97.69
$99.45
$101.24
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
2026
2027
2028
2029
RHC Cap
Average Cost

Based on this disparity between costs and Medicare payment, why are independent RHCs not closing or transitioning more rapidly?

In some states, it appears that Medicaid reimbursement, which often does not distinguish between Independent and Provider-based RHC status, is the incentive to remain in the RHC program as an independent RHC.

Provider-Based Average Payment Per Visit is $207 per Visit



Rural Health Clinic Modernization

NARHC is promoting the Rural Health Clinic Modernization Act of 2018

Raise the Cap on Rural Health Clinic Payments.

Increase the upper limit (or cap) on RHC reimbursement incrementally over 3 years.

$105 in 2020 (currently $84.70)
$110 in 2021
$115 in 2022

S. 1037 - Rural Health Clinics Modernization Act

- **Sec. 2 Modernizing Physician, Physician Assistant, and Nurse Practitioner Utilization Requirements.**
- Modernizes RHC physician supervision requirements by aligning them to state scope of practice laws governing PA and NP practice. Now that all states have Practice Acts governing PA and NP scope of practice, federal standards are unnecessary. Allows PAs and NPs to practice to the top of their license without unnecessary federal supervision requirements that apply only because the PA or NP is practicing in an RHC.
- **Sec. 3 Removing Outdated Laboratory Requirements.**
- Removes a requirement that RHCs must "directly provide" certain lab services on site, and allows RHCs to satisfy this requirement if they have *prompt access* to the required lab services.
- **Sec. 4 Allowing Rural Health Clinics the Flexibility to Contract with Physician Assistants and Nurse Practitioners.**
- Removes a redundant requirement that RHCs employ a PA or NP (as evidenced by a W2) and allows RHCs to satisfy the PA, NP, or CNM utilization requirements through a contractual agreement if they choose to do so.
- **Sec. 5 Allow Rural Health Clinics to be the Distant Site for a Telehealth Visit.**
- Allows RHCs to offer telehealth services as the distant site (where the provider is located) and bill for such telehealth services as RHC visits. Currently, RHCs are limited to being the originating site (where patient is located).
- **Sec. 6 Creating a State Option for Rural Designation**
- Gives new authority to States (with HHS certification) to define areas as rural for the purposes of establishing a RHC. Similar authority currently exists for state designation of shortage areas.
- **Sec. 7 Raising the Cap on Rural Health Clinic Payments.**
- Beginning in CY 2020, increase the upper limit (or cap) on RHC reimbursement to $105 per visit, in CY 2021 to $110 per visit and in CY 2022, to $115 per visit. Thereafter, cap is adjusted annually by MEI.

Section 2

Modernize Physician, Physician Assistant, and Nurse Practitioner Utilization Requirements

Modernizes physician supervision requirements in RHCs by aligning scope of practice laws with state law. Allows PAs and NPs to practice up to the top of their license without unnecessary federal supervision requirements that apply only because the PA or NP is practicing in a RHC.

Rural Health Clinics would still be required to have a physician who serves as the Medical Director of the RHC

Section 3

Remove Outdated Laboratory Requirements

Removes a requirement that RHCs must demonstrate the ability to directly provide certain lab services on site, and allow RHCs to satisfy this certification requirement if they have *prompt access* to lab services.

Required Lab services include:

- Chemical examinations of urine by stick or tablet method or both (including urine ketones)
- Hemoglobin or hematocrit
- Blood glucose
- Examination of stool specimens for occult blood
- Pregnancy tests
- Primary culturing for transmittal to a certified laboratory

Section 4

Allow Rural Health Clinics the Flexibility to Contract with PAs and NPs

Removes a redundant requirement that RHCs employ* a PA or NP (as evidenced by a W2) and allows RHCs to satisfy the PA, NP, or CNM utilization requirements through a contractual agreement if they chose to do so.

*This DOES NOT remove the requirement that RHCs must use/utilize PAs or NPs but simply provides flexibility in how they are "employed".

Section 5

Allow Rural Health Clinics to be the Distant Site for a Telehealth Visit

Currently, RHCs are limited to being the "originating" site for Medicare covered telehealth services

Allow RHCs to offer telehealth services as the distant site (where the provider is located) and bill for such telehealth services as RHC visits.

Section 6

Create a State Option for Rural Designation

Grants new authority to States to define additional areas as rural for the purposes of establishing a RHC.

Retains federal designations (non-urbanized) but as is the case with underserved designations, creates a "state option".

Section 7

Rural Health Clinic Modernization

NARHC is promoting the Rural Health Clinic Modernization Act of 2018

Raise the Cap on Rural Health Clinic Payments.

Increase the upper limit (or cap) on RHC reimbursement incrementally over 3 years.

$105 in 2020 (currently $84.70)
$110 in 2021
$115 in 2022

How Much will this cost?

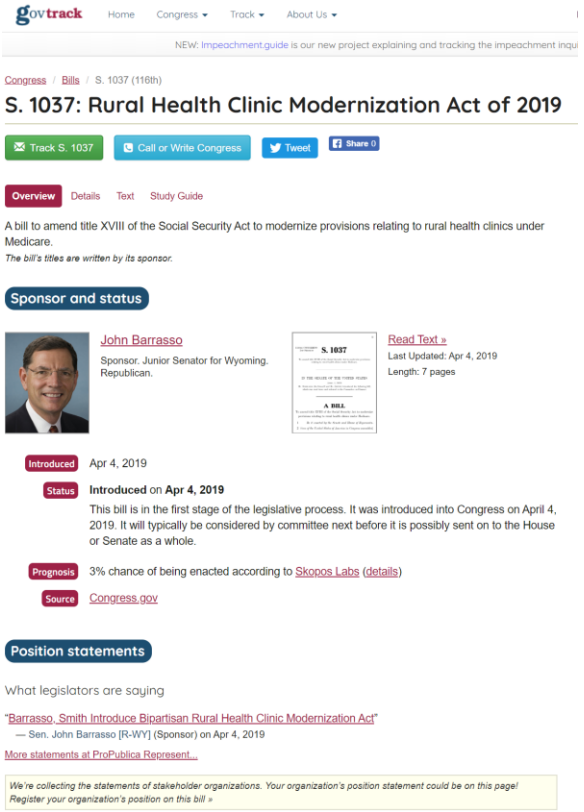
We believe – and the data supports the conclusion – that the shift in encounter volume from independent to provider-based RHCs will happen *half* as quickly over the next 10 years compared to current law if Congress adopts the Barrasso proposal.

This is where we believe the legislation could achieve savings.

By shifting Medicare encounter volume from higher paid provider-based encounters to lower paid independent encounters savings will accrue to the Medicare program.

What are the chances?

The odds of the bill itself passing are very low, but if added to another bill such as Surprise Medical Bills or Pharmaceutical costs the percentage goes up to 50% to 60%.


govtrack Home Congress Track About Us

NEW: Impeachment.guide is our new project explaining and tracking the impeachment inqui

Congress / Bills / S. 1037 (116th)

S. 1037: Rural Health Clinic Modernization Act of 2019

Track S. 1037 | Call or Write Congress | Tweet | Share 0

Overview Details Text Study Guide

A bill to amend title XVIII of the Social Security Act to modernize provisions relating to rural health clinics under Medicare.

The bill's titles are written by its sponsor.

Sponsor and status

John Barrasso

Sponsor. Junior Senator for Wyoming. Republican.

Read Text »

Last Updated: Apr 4, 2019

Length: 7 pages

Introduced Apr 4, 2019

Status **Introduced** on **Apr 4, 2019**

This bill is in the first stage of the legislative process. It was introduced into Congress on April 4, 2019. It will typically be considered by committee next before it is possibly sent on to the House or Senate as a whole.

Prognosis 3% chance of being enacted according to Skopos Labs (details)

Source Congress.gov

Position statements

What legislators are saying

"Barrasso, Smith Introduce Bipartisan Rural Health Clinic Modernization Act"

— Sen. John Barrasso [R-WY] (Sponsor) on Apr 4, 2019

More statements at ProPublica Represent...

We're collecting the statements of stakeholder organizations. Your organization's position statement could be on this page! Register your organization's position on this bill »

https://www.govtrack.us/congress/bills/116/hr2788

Email Nathan Baugh at baughn@capitolassociates.com

S. 1037 - Rural Health Clinics Modernization Act

What can you do?

Call or Write your Congressman

Who represents you in Washington?
To find out who your representatives/senators are and their contact information visit:
https://www.govtrack.us/congress/members
Below are some resources to help you advocate to your Congressional delegation.

Click Here - RHC Modernization Act Policy Narrative
Click Here - The RHC Modernization Act Section-by-Section
Click Here - Full Text of RHC Modernization Act
Click Here - Sample Letter Asking Senators For Their Support
Click Here - Sample Letter Asking For Support from the House of Representatives
Click Here - Sen. Barrasso Press Release
Click Here - Sen. Smith Press Release
Click Here - National Rural Health Association Endorsement
Click Here - Missouri Association of Rural Health Clinics Endorsement
Click Here - Indiana Rural Health Association Endorsement
Click Here - Smith/Sewell/McMorris Rodgers/Loebsack press release (5/16/2019)

https://www.web.narhc.org/narhc/RHC_Modernization_Act_Advocacy.asp

S. 1037 - Rural Health Clinics Modernization Act

We should know something in early December or possibly January 2020 at the latest.

Changes to the RHC Program

CMS plan to resolve Medicare overpayments

CMS and Palmetto have a plan to resolve the overpayments related to Medicare Advantage Plans. The good news is the MACS (mainly Cahaba) paid back $26 million of the overpayments and there will be some claims that RHC can bill for even though the timely filing deadline has passed. The bad news are there are some claims that the MAC did not reimburse CMS and cannot be rebilled and will result in a settlement from rural providers including RHCs.

The process was outlined in a letter from CMS and posted on the Palmetto GBA website:

CMS Plan for Medicare Advantage Overpayments

CMS plan to resolve Medicare overpayments (2)

Here are exerts from the letter outlining the plan and when certain documents will be send to rural providers and RHCs.

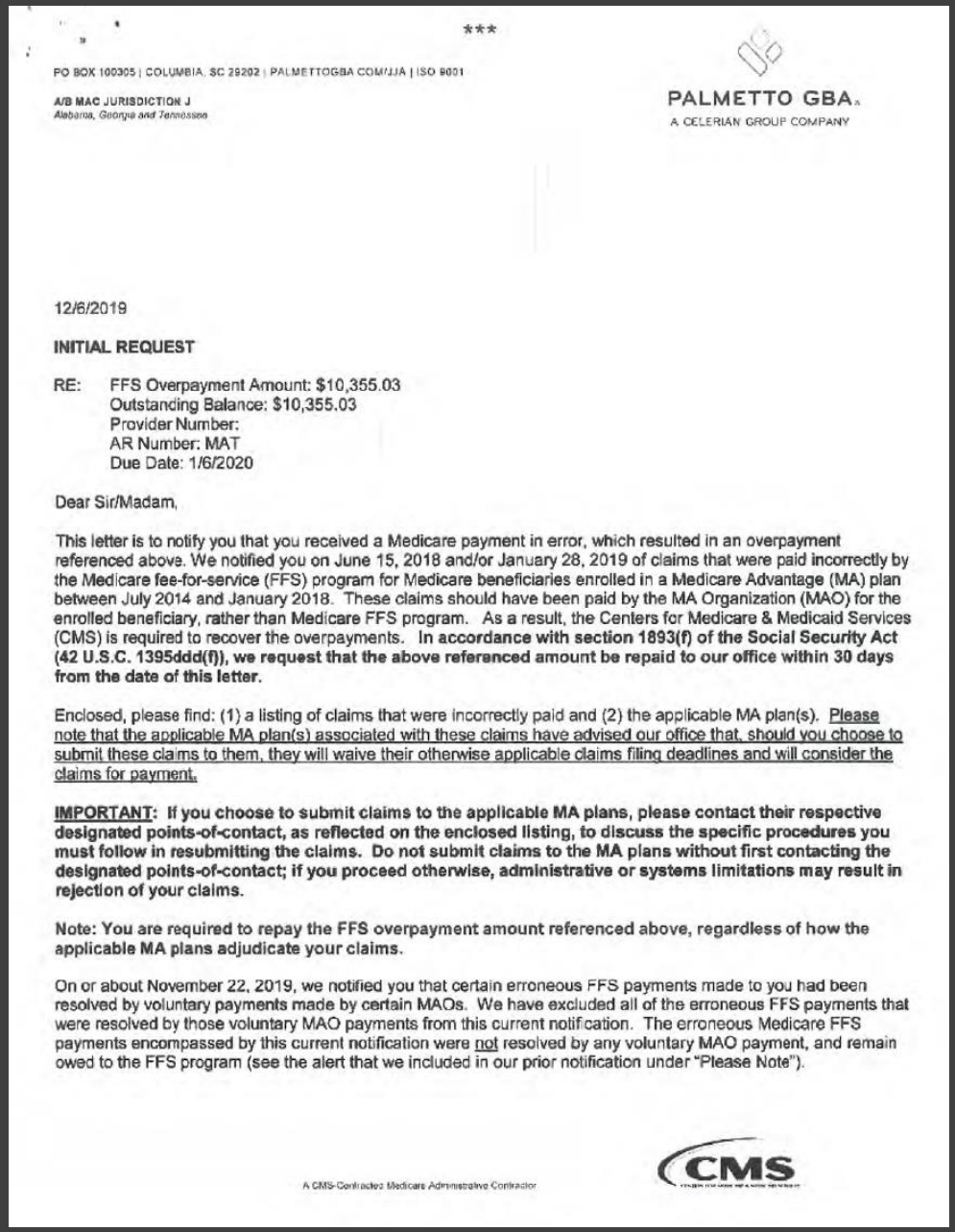
"The first letter is scheduled to go out later this month and will identify those overpayments relating to this issue that have been voluntarily resolved by several dozen Medicare Advantage organizations, which together sponsor nearly 200 plans. These MA organizations agreed to voluntarily give back $26 million to original Medicare to resolve 133,000 erroneous claims, according to the notice and Georgia Health News.

The second letter is scheduled to go out in December and will identify the overpayments that providers may rebill to three dozen Medicare Advantage organizations, which together sponsor 108 plans. The notice says these MA organizations agreed to allow providers to bill their claims again "or otherwise pursue payment, even though their respective claims filing deadlines had passed."

CMS plan to resolve Medicare overpayments (3)

- **The third letter, scheduled to go out in January, addresses about $12 million of the MA plan overpayments that were unresolved because Medicare Advantage organizations did not make a voluntary repayment or arrange for claims to be rebilled. In the third letter, there will be a settlement offer from CMS related to the unresolved claims, according to the notice.**
- **"Providers that accept the CMS settlement offer will retain a sizable portion of the original payments but will need to repay the balance specified in the settlement offer," the notice states. "Providers that do not accept the CMS settlement offer will receive a Medicare demand letter for the full balance, which they will need to repay; however, these providers will be permitted to pursue appeals on any of the claims if they wish to."**

Copy of Letter from Palmetto Regarding Medicare Advantage Plan Overpayments



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PO BOX 100305 | COLUMBIA, SC 29202 | PALMETTOGBA.COM/JJA | ISO 9001

A/B MAC JURISDICTION J
Alabama, Georgia and Tennessee

PALMETTO GBA
A CELERIAN GROUP COMPANY

12/6/2019

INITIAL REQUEST

RE: FFS Overpayment Amount: $10,355.03
Outstanding Balance: $10,355.03
Provider Number:
AR Number: MAT
Due Date: 1/6/2020

Dear Sir/Madam,

This letter is to notify you that you received a Medicare payment in error, which resulted in an overpayment referenced above. We notified you on June 15, 2018 and/or January 28, 2019 of claims that were paid incorrectly by the Medicare fee-for-service (FFS) program for Medicare beneficiaries enrolled in a Medicare Advantage (MA) plan between July 2014 and January 2018. These claims should have been paid by the MA Organization (MAO) for the enrolled beneficiary, rather than Medicare FFS program. As a result, the Centers for Medicare & Medicaid Services (CMS) is required to recover the overpayments. **In accordance with section 1893(f) of the Social Security Act (42 U.S.C. 1395ddd(f)), we request that the above referenced amount be repaid to our office within 30 days from the date of this letter.**

Enclosed, please find: (1) a listing of claims that were incorrectly paid and (2) the applicable MA plan(s). Please note that the applicable MA plan(s) associated with these claims have advised our office that, should you choose to submit these claims to them, they will waive their otherwise applicable claims filing deadlines and will consider the claims for payment.

IMPORTANT: If you choose to submit claims to the applicable MA plans, please contact their respective designated points-of-contact, as reflected on the enclosed listing, to discuss the specific procedures you must follow in resubmitting the claims. Do not submit claims to the MA plans without first contacting the designated points-of-contact; if you proceed otherwise, administrative or systems limitations may result in rejection of your claims.

Note: You are required to repay the FFS overpayment amount referenced above, regardless of how the applicable MA plans adjudicate your claims.

On or about November 22, 2019, we notified you that certain erroneous FFS payments made to you had been resolved by voluntary payments made by certain MAOs. We have excluded all of the erroneous FFS payments that were resolved by those voluntary MAO payments from this current notification. The erroneous Medicare FFS payments encompassed by this current notification were not resolved by any voluntary MAO payment, and remain owed to the FFS program (see the alert that we included in our prior notification under "Please Note").

Copy of Letter from Medicare Advantage Plan Regarding Medicare Advantage Plan Overpayments

MOLINA HEALTHCARE

August 29, 2019

CALL TO ACTION – RESPONSE NEEDED IN 90 DAYS

RE: CMS request to waive timely filing requirements

Dear

Earlier this year, CMS notified Molina that certain Medicare claims with a date of service (DOS) between CY2014 through CY2017 were mistakenly paid under the original Medicare Fee for Service (FFS) Program. These claims were for services received by Medicare beneficiaries that belonged to Molina's Medicare Advantage Plan and should have been submitted to Molina for processing. Pursuant to the contract you have with Molina, the standard timely filing requirement for these claims has expired.

As a result of what occurred, Molina has agreed to waive the standard timely filing requirement for the attached list of claims, because this occurred due to no fault of the provider.

As a result of Molina waiving the standard timely filing requirement, provider will have 90 days from receipt of this of this letter to resubmit the attached list of claims for payment. If provider does not resubmit the attached list of claims within 90 days of receiving this letter, then Provider will not be eligible to receive payment. *Please include a copy of the attached claims with your submission.*

If you choose to decline the option to resubmit claims, no further action is needed.

This letter does not affect the timely filing requirement for any other claims besides the attached list of claims.

Please address claims to:

Molina Healthcare
ATT: Support Services, Daline/Kelly
200 Oceangate, Suite 100, Long Beach, CA 90802

For any questions please call Daline Abdullah, Medicare Claims Processing at 888-562-5442 ext. 126518.

Palmetto Update on Medicare overpayments

01/03/2020: The Phase III Settlement Offer Letters were mailed to affected providers earlier today (January 3, 2020). These CMS settlement offers are intended to address all remaining unresolved "MA overpayment" claims. Providers have sixty days (until March 3, 2020) to accept CMS's settlement offer. See the 12/20/2019 CPIL update for additional details.

As was the case for the earlier Phase I and Phase II letters, these third (Phase III) letters are directed to the attention of each provider's Chief Executive Officer (stamped in red letters on the envelope). Providers need to be alert for these letters, given their time-sensitivity. Only providers affected by Phase III of CMS's approach to resolving the MA overpayments will receive these letters.

- https://www.palmettogba.com/palmetto/providers.nsf/DocsR/Providers~JJ%20Part%20A~Browse%20by%20Topic~Claims%20Processing%20Issues%20Log~Current%20Issues~AZ9J8M2780?open

Medicare Advantage (MA) Plan Overpayments - Update

Current Status

01/03/2020: The Phase III Settlement Offer Letters were mailed to affected providers earlier today (January 3, 2020). These CMS settlement offers are intended to address all remaining unresolved "MA overpayment" claims. Providers have sixty days (until March 3, 2020) to accept CMS's settlement offer. See the 12/20/2019 CPIL update for additional details.

As was the case for the earlier Phase I and Phase II letters, these third (Phase III) letters are directed to the attention of each provider's Chief Executive Officer (stamped in red letters on the envelope). Providers need to be alert for these letters, given their time-sensitivity. Only providers affected by Phase III of CMS's approach to resolving the MA overpayments will receive these letters.

Situation Identified May 7, 2018
The original article entitled, Potential Medicare Advantage (MA) Plan Overpayment was published on May 7, 2018, and updated on June 12, 2018.

Previous Status:
12/20/2019: **The Third and final letter — which will be a Settlement Offer on CMS letterhead — will be mailed to affected providers on January 3, 2020.** This CMS letter will contain a settlement offer covering all remaining unresolved "MA overpayment" claims. Key points are:

- Provider will receive the Third Letter for unresolved MA overpayment claims where the MAO opted against making a voluntary payment or arranging for rebilling of claims
- The Third Letter will contain a CMS settlement for the unresolved MA overpayment claims and will contain a listing of the specific claims included in CMS's settlement offer
- Providers receiving a CMS settlement offer will have sixty (60) days to respond
- Providers that accept the CMS settlement offer will retain a sizable portion (60%) of the original payments but will need to repay the balance specified in the settlement offer
- Providers that do not accept the CMS settlement offer will receive a Medicare demand letter for the full balance, which they will need to repay; however, these providers will be permitted to pursue appeals on any of the claims if they wish to

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KNOWLEDGE • RESOURCES • TRAINING

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update

MLN Matters Number: MM11575 | Related Change Request (CR) Number: 11575

Related CR Release Date: December 20, 2019 | Effective Date: January 1, 2020

Related CR Transmittal Number: R263BP | Implementation Date: January 23, 2020

PROVIDER TYPES AFFECTED

This MLN Matters Article is for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11575 revises Medicare Benefit Policy, Chapter 13 (Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services) to clarify payment and other policy information.

BACKGROUND

The 2020 update of the Medicare Benefit Policy Manual, Chapter 13 provides information on requirements and payment policies for RHCs and FQHCs, as authorized by Section 1861(aa) of the Social Security Act. The updated manual Chapter 13 is an attachment to CR 11575. The manual changes are as follows:

Section 110.3 - Graduate Medical Education - The Centers for Medicare & Medicaid Services (CMS) revised this section to clarify that **Freestanding** RHCs and FQHCs may receive direct Graduate Medical Education (GME) payment for residents if the RHC or FQHC incurs the salaries and fringe benefits (including travel and lodging expenses where applicable) of residents training at the RHC or FQHC.

Section 120.1 - Provision of Incident to Services and Supplies - CMS clarified language in this section to show that among the services that are not considered incident to include the services provided by a third party under contract to the RHC or FQHC.

Section 180 - Physical Therapy, Occupational Therapy, and Speech Language Pathology Services - CMS amended this section to clarify that Physical Therapy (PT), Occupational Therapy (OT), and Speech Language Pathology (SLP) services furnished by an RHC or

Page 1 of 3

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Learning Network

Med-Learn Matters Changes to Chapter

Effective Date: January 1, 2020

https://tinyurl.com/vfsqjl2

FQHC practitioner or furnished incident to a visit with an RHC or FQHC practitioner are not billable visits.

Section 230.2 – General Care Management Services – Chronic Care - CMS revised this section to state that Beneficiary consent to receive care management services must be obtained either by or under the direct supervision of the RHC or FQHC primary care practitioner. The consent may be written or verbal and must be documented in the patient's medical record before furnishing Chronic Care Management or Behavioral Health Integration services.

Section 230.3 – Psychiatric Collaborative Care Model (CoCM) Services - CMS revised this section to emphasize that Beneficiary consent to receive care management services must be obtained either by or under the direct supervision of the RHC or FQHC primary care practitioner. The consent may be written or verbal and must be documented in the patient's medical record before furnishing psychiatric CoCM services.

ADDITIONAL INFORMATION

The official instruction, CR 11575, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/R263BP.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
December 23, 2019	Initial article released.

Med-Learn Matters Changes to Chapter

Effective Date: January 1, 2020

https://tinyurl.com/vfsqjl2

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update

A new MLN Matters Article (MM11575) on Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update (PDF) is available. Learn about clarifications to payment and policy.

Section 110.3 - Graduate Medical Education - The Centers for Medicare & Medicaid Services (CMS) revised this section to clarify that **Freestanding** RHCs and FQHCs may receive direct Graduate Medical Education (GME) payment for residents if the RHC or FQHC incurs the salaries and fringe benefits (including travel and lodging expenses where applicable) of residents training at the RHC or FQHC.

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Section 180 - Physical Therapy, Occupational Therapy, and Speech Language Pathology Services - CMS amended this section to clarify that Physical Therapy (PT), Occupational Therapy (OT), and Speech Language Pathology (SLP) services furnished by an RHC or FQHC practitioner or furnished incident to a visit with an RHC or FQHC practitioner are not billable visits.

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Can RHCs Report CPT Category II codes that track performance measurement on the UB-04.

A. Yes

B. No

C. Huh?

How to Report Quality Measures in RHCs Quality Payment Program: Qualified Registries and QCDRs for CY 2020

CMS posted the CY 2020 approved Qualified Registries and Qualified Clinical Data Registries (QCDRs) qualified postings. These entities collect clinical data from individual Merit-based Incentive Payment System (MIPS)-eligible clinicians, groups, and/or virtual groups and submit data to CMS.

- Qualified Registries Qualified Posting
- QCDRs Qualified Posting

For More Information:

- Resource Library webpage
- Contact qpp@cms.hhs.gov or 866-288-8292

Snapshot of Quality Payment Registries

Disclaimer: The Merit-based Incentive Payment System (MIPS) Final approved 2020 Qualified Registries List is a list of all entities that are authorized by the Centers for Medicare & Medicaid Services (CMS) to submit Quality Measures, Promoting Interoperability Measures, and/or Improvement Activities on behalf of MIPS eligible clinicians, groups, and/or virtual groups for purposes of MIPS for the 2020 performance year. ***Qualified Registries will provide performance category feedback at least four times a year for all MIPS eligible clinicians*** *. These vendors are approved as Qualified Registries by CMS through the MIPS self-nomination process. CMS has not otherwise evaluated the capabilities, quality, or any other features of any specific entity or its products referenced on the MIPS Final approved 2020 Qualified Registries list. Reference to any specific entity, commercial product, process, or service (collectively, "specific entity or its products") on the MIPS Final approved 2020 Qualified Registries list does not constitute any endorsement or recommendation of the specific entity or its products by CMS or the United States Government. Such reference does not imply that a specific entity or its products meets any other federal health care program requirements applicable to the entity or its products or to MIPS eligible clinicians, groups, and/or virtual groups on whose behalf the entity submits data to CMS. Prior to selecting or using any specific entity or its products, MIPS eligible clinicians, groups, and/or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.*

Vendor	Quality	Improvement Activities	Promoting Interoperability
+1 ConfidentHealth MDrun MIPs and ACO Reporting Registry	X	X	X
A2C Medical	X	X	X
AAD's DataDerm™	X	X	X
AAOE Empower Registry	X	X	X
AAO-HNSF Reg-ent Registry	X	X	X
abeo Quality Registry AQR	X		
Able Health Qualified Registry	X	X	X
ACO Health Solutions	X	X	X
Acurus Solutions, Inc.	X	X	X
Advance Qualified Registry	X	X	X
Advanced Integrated Registry (AIR)	X	X	X
ADVOCATE	X	X	X
Affordable QR	X	X	X
All-Measures MIPS Registry	X	X	X
Alpha II Registry	X	X	X
AltuMed	X	X	X
American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight)	X	X	X
American Health IT, LLC	X	X	X
American Vein and Lymphatic Society PRO Registry	X	X	X
Analitico	X	X	X
Anesthesia Quality Institute (AQI) National Anesthesia Clinical Outcomes Registry (NACOR)	X	X	
Apervita Quality Registry	X		X
APMD Quality Group	X	X	
Apogee Medical Management Quality Reporting Registry	X	X	
ArborMetrix Qualified Registry	X	X	X
Arcadia Qualified Registry	X	X	X
Ascend BPO Services	X	X	X
ASP.MD Inc	X	X	X
athenahealth **CMS has taken Remedial Action against this Qualified Registry for 2019. Please note, this remedial action may be resolved during the 2020 MIPS performance period, and updated information may be posted in future iterations of this qualified posting.**	X		
Avant Garde Healthcare Services	X	X	X

Are RHCs subject to MIPS/MACRA Reporting Requirements?

A. Yes

B. No

C. Possibly

Are RHCs subject to MIPS?

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) MIPS payment adjustments do not apply to facility payments to RHCs and FQHCs. Clinicians providing items and services in RHCs or FQHCs and billing under those respective payment systems will not be required to participate in MIPS or be subject to MIPS payment adjustments. However, if the clinicians practicing in RHCs or FQHCs bill services under the PFS, they may be expected to participate in MIPS and subject to MIPS payment adjustments.

You must participate in MIPS (unless otherwise exempt) if, in both 12-month segments of the MIPS Determination Period, you:

- Bill more than $90,000 for Part B covered professional services, and
- See more than 200 Part B patients, and;
- Provide 200 or more covered professional services to Part B patients.

Summary of RHC Rule Changes from NARHC Newsletter

Final Rule Changes

Patient Policies, Program Evaluations, Emergency Preparation

CMS Final Rule for RHCs and FQHCs! Policy and Procedure Review, Annual Evaluation, and Emergency Preparedness requirements have been changed.

Document Number: 2019-20736
"Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care."

The new final rule does the following:

- Changes the Policy Review and Annual Evaluations to biennial requirements.
- Changes the requirement for facilities to review their emergency preparedness program to at least biennial.
- Eliminates the need to document outreach efforts to local emergency resources, but facilities will "still be required to include a process for cooperation and collaboration" with them.
- Requires facilities to provide training biennially or every 2 years, after facilities conduct initial training on their emergency program.
- Requires that providers of outpatient services *conduct only one testing exercise per year*, that either a community-based full-scale exercise (if available) *or* conduct an individual facility-based functional exercise every other year.
- In the opposite years, these providers may conduct the testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.
- If a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event.

https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and

The following are now biennial, not annual requirements:

- Review of Patient Care Policies §491.9(b)(4)
- RHC and FQHC Program Evaluation – §491.11(a)
- Annual Review of Emergency Preparedness Program – §491.12
- Annual Emergency Preparedness Training Program §491.12(d)(1)(ii)

The requirements for the following have been eased:

- Documentation of Cooperation Efforts – §491.12(a)(4) has been eliminated
- Annual Emergency Preparedness Testing – §491.12(d)(2) – only one required per year

Charles James Jr.
North American Healthcare Management Services
Northamericanhms.com

https://files.constantcontact.com/d9ff9a02301/c7e27ce5-ff34-4d28-86cf-434c408d7bae.png

Medicare Beneficiary Identifiers (MBI)

Most HICN Claims Reject – Regardless of Date Service

Use Medicare Beneficiary Identifiers (MBIs) now to avoid claim and eligibility transaction rejects. Effective January 1, 2020, regardless of the date of service on the Medicare transaction, most Social Security Number – based Health Insurance Claim Number (HICN) Medicare transactions will reject with a few exceptions.

If you do not use MBIs on claims after January 1, you will get:

- Electronic claims reject codes: Claims Status Category Code of A7 (acknowledgment rejected for invalid information), a Claims Status Code of 164 (entity's contract/member number), and an Entity Code of IL (subscriber)
- Paper claims notices: Claim Adjustment Reason Code (CARC) 16 "Claim/service lacks information or has submission/billing error(s)" and Remittance Advice Remark Code (RARC) N382 "Missing/incomplete/invalid patient identifier"

Thank you for transitioning to MBIs during the 21 month transition period, protecting your patients from identity theft.

- You are currently submitting 87% of claims with MBIs.
- If your patient doesn't have their new card, give them the Get Your New Medicare Card flyer in English or Spanish.
- Get MBIs through the MAC portals (sign up (PDF)) now and after the transition period. You can also find the MBI on the remittance advice.

See the MLN Matters Article (PDF) for more information on getting and using MBIs.

RHCs Excluded from Principal Care Management Benefit in 2020

Conflicting Statements from CMS in 2020 Final Rule

In 2020, Rural Health Clinics may not bill for Principal Care Management.

Principal Care Management (PCM) is a new benefit that Medicare will cover in 2020. It is very similar to the chronic care management (CCM) benefit, except for the fact that patients can qualify for principal care management services with only **one** chronic condition, whereas CCM services can only be provided to patients with at least **two** chronic conditions.

The 2020 Medicare Physician Fee Schedule contained conflicting language that at one point stated that rural health clinics *could* bill for PCM services using our CCM or "care management" G-code G0511, and then at another point stated that RHCs *could not* bill for PCM. NARHC and others pointed out these conflicting sections to CMS and they issued a correction on January 2nd which clarified that RHCs may not bill for Principal Care Management with our G0511 code or any other code.

While we were disappointed that CMS clarified that we could not bill for PCM, due to the way CMS prices the reimbursement for G0511, if CMS had allowed RHCs to bill for PCM services it may have lowered reimbursement for G0511.

NARHC believes that CMS should expand PCM services to RHCs and we will be asking CMS to expand that benefit for 2021. We will also be pressing that CMS find a way to expand the PCM benefit to RHCs without hurting G0511 reimbursement.

While most Medicare beneficiaries can qualify for CCM by having at least two chronic conditions, it makes no sense that Medicare beneficiaries with only one chronic condition may not receive this service simply because their clinician works in a rural health clinic.

We will be working with CMS to fix these issues in 2021, but in the meantime, make sure that all your care management patients have at least two chronic conditions.

Nathan Baugh
Director of Government Affairs
National Association of Rural Health Clinics
Nathan.Baugh@narhc.org

Appropriate Use Criteria (AUC)

The appropriate use criteria mandate is a Medicare program (which Congress created in 2014) designed to ensure that orders of advanced imaging are appropriate given the clinical condition of the patient. Any time a RHC clinician orders an advanced image (MRI, CT scan, nuclear medicine, or PET scan), the clinician must verify that this advanced image order is in fact necessary and proper.

The ordering professional is required to use a "qualified clinical decision support mechanism" (qCDSM) to query sets of "appropriate use criteria" in order to verify if the advanced image they want to order is clinically appropriate. In other words, your clinicians will need to verify at the time of the order, either through a qCDSM portal embedded in your EHR system, or through a free online portal that the advanced image is necessary for that Medicare patient.

While this may sound a lot like prior authorization, it is important to note that even if the AUC consultation indicates that the image is **not** appropriate, Medicare will still reimburse the imaging facility and radiologist for that image. After several years of data is collected by the Centers for Medicare and Medicaid Services (CMS), outlier ordering professionals (those with the highest rates of ordering imaging that is deemed not appropriate) will be subject to prior authorization.

https://www.web.narhc.org/News/28162/New-Medicare-Mandate-Appropriate-Use-Criteria

Appropriate Use Criteria (AUC) (2)

When does the program start?

2020 is the beginning of a one-year "Educational and Operational Testing Period." During 2020, advanced imaging claims may include ~ but are not required to have ~ information regarding the AUC consultation. After the Educational and Operational Testing Period ends, advanced imaging claims must include AUC information in order to be paid. Unless CMS extends the educational period, imaging facilities will likely require that you provide them this information in 2021, or else they will not perform the requested advanced image (because they won't get paid if they don't put this information on their claim).

Does this policy apply to all advanced imaging?

No. This policy only applies to outpatient advanced imaging performed in an "applicable setting" and paid through an "applicable payment system." Critical Access Hospitals are not paid through an applicable payment system and are thus exempt from this program.

Appropriate Use Criteria (AUC) (3)

Are there any other exceptions?

Yes. Ordering professionals or clinicians will not have to consult AUC if: 1-the patient is deemed to be in an emergency medical condition; or 2-if the ordering professional has a hardship due to insufficient internet access, EHR or CDSM vendor issues, or extreme and uncontrollable circumstances (such as a natural disaster).

Does this apply to Medicare Advantage patients?

No. The AUC mandate is only applicable for traditional Medicare patients.

The Omnibus Burden Reduction Final Rule

Finalizes the following:

- **"Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction," published September 20, 2018 (83 FR 47686);**

https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and

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When are these rules effective?

Effective date: **These regulations are effective on November 29, 2019.**

The Regulation on Program Evaluation

- **D. RURAL HEALTH CLINIC (RHC) AND FEDERALLY QUALIFIED HEALTH CENTER (FQHC) REVIEW OF PATIENT CARE POLICIES**

- **We are revising the requirement at § 491.9(b)(4) that RHC and FQHC patient care policies be reviewed at least annually by a group of professional personnel, to review every other year in order to reduce the frequency of policy reviews.**

- **E. RHC AND FQHC PROGRAM EVALUATION**
- We are revising the requirement at § 491.11(a) by changing the **frequency of the required RHC or FQHC evaluation from annually to every other year.**

Comments on the Program Evaluation Rule

Comment: Overall, the majority of comments submitted regarding this topic expressed support for both of the proposed changes to require biennial provision of services policy reviews and clinic or center total program evaluation. Some of the commenters were completely supportive of the proposed biennial change, while some of the commenters stated they were unsure whether it will provide meaningful burden reduction. Other commenters were appreciative of the CMS goal to reduce burden on the RHC or FQHC and stated that the flexibility and opportunity to allow the clinic or center to decide how to most appropriately use their staff time and resources is critical to maintaining the highest standard of care for their patients. One commenter suggested that, in addition to revising the time frame for review, CMS should also reduce the burden of this regulation by removing the requirement that someone in the group of professional personnel that reviews the policies must be from outside the clinic or center's staff.

Contact: CAPT Jacqueline Leach, USPHS, 410-786-4282

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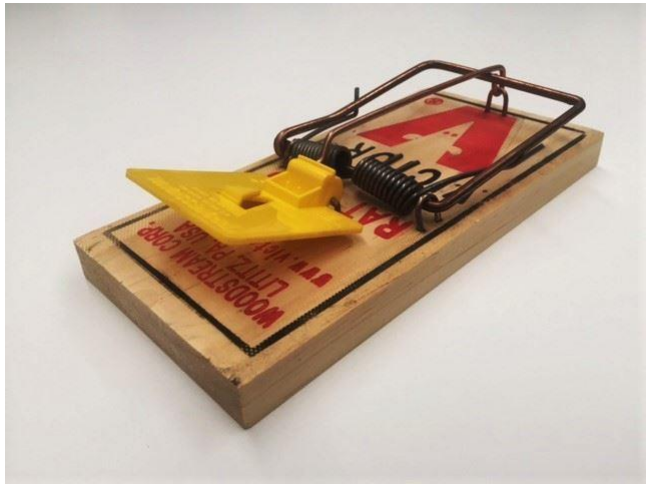
Program Evaluation is now every two years

The program evaluation and review of patient care policies requirements are reduced from annually to every two years.



Watch out for the trap

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Program Evaluation is now every two years (Continued)

Don’t forget to change your RHC Policy and Procedure Manual to reflect the new regulation as you may receive a deficiency for not following your Policy Manual

Insert the new Policy in your P & P manual

Biennial Program Evaluation Policy

Policy Number	810
Subject	Biennial Program Evaluation
Effective Date	XX/XX/XXXX
Review Date	XX/XX/XXXX

Policy:
Clinic Name carries out a biennial program evaluation of its total program drawing upon any technical assistance resources that may be available. A consultant specializing in rural health clinic delivery systems may participate in this process.

Biennial Program Evaluation Elements

1. **Utilization of Clinic Services.** The Office Manager will collect all utilization data including the number of patients served and the volume of services for the committee to review.
2. **Patient Care Guidelines.** The Medial Director and Physician Assistant/Nurse Practitioner will review the patient care policies on a biennial basis and make changes where appropriate. Policies reviewed include direct clinical services, clinic services by arrangement, guidelines for medical management of health problems and rules relating to drugs and biologicals.
3. **Chart Audit.** Open and closed clinical records will be reviewed and all changes will be communicated to the clinical providers.
4. **Review of Policy and Procedures.** The policies and procedures of the clinic will be reviewed and the need for updating will be evaluated.
5. **Walk-through of the Clinic.** There will be a walkthrough of the clinic to determine if the policies and procedures are being followed.

Biennial Program Evaluation Committee

1. Members of the Program Evaluation Committee will include the members of the Clinic Name Advisory Committee as described in Section 1 of the Policy and Procedure Manual.
2. The Medical Director will serve as the chairman of the evaluation committee. The committee will include a Physician Assistant/Nurse Practitioner, the Office Manager, and at least one community member.
3. The responsibility and purpose of the Program Evaluation Committee will include the following:
    a. Evaluation of the utilization of clinic services, including at least the number of patients served and the volume of services to determine appropriateness of utilization.
    b. Evaluation of the all policies contained in the Administrative Manual and Clinical Manual with regards to appropriateness and whether or not the policies were followed.

http://www.ruralhealthclinic.com/s/Biennial-Program-Evaluation-Policy-810-Template-Updated-10-1-2019.docx

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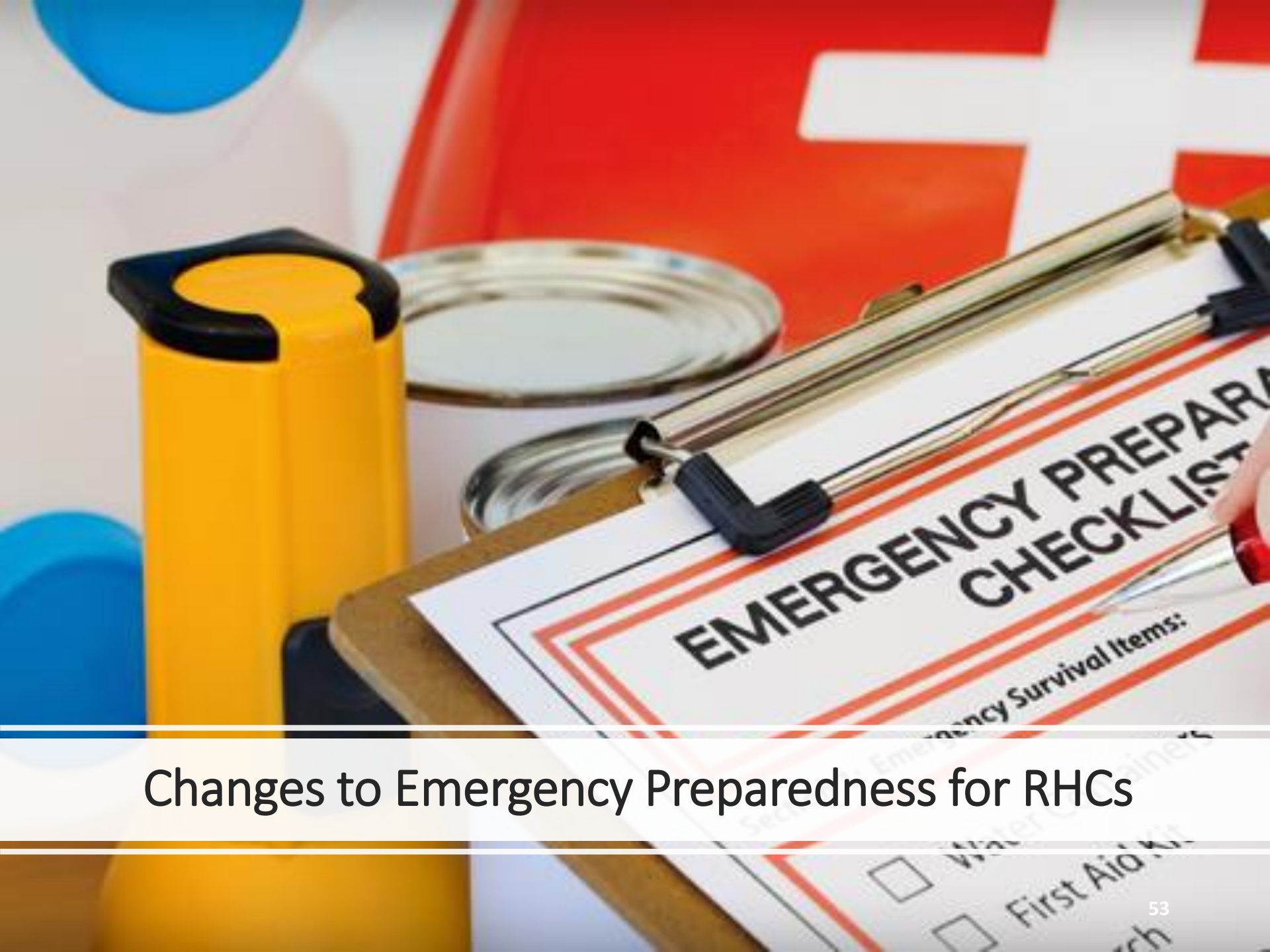
Projected Savings of Program Evaluation Changes

We discussed the burden reduction for our revision of § 491.9(b)(4) “review of patient care policies” requirements imposed on RHCs and FQHCs in the ICR section, which is an estimated savings of $7.3 million biennially, or **approximately $3.7 million annually.**

In addition, the burden reduction for our revision of § 491.11(a) “program evaluation” requirements imposed on RHCs and FQHCs in the ICR section of this rule, which is an estimated savings of $9.9 million biennially, or **approximately $5 million annually.**



Changes to Emergency Preparedness for RHCs

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The following four changes are made to the Emergency Preparedness requirements for RHCs

- *Emergency program:* decreased the requirements for RHCs to conduct an annual review of their emergency program to a biennial review.
- *Emergency plan:* Eliminating the requirement that the emergency plan include documentation of efforts to contact local, tribal, regional, State, and federal emergency preparedness officials and a facility's participation in collaborative and cooperative planning efforts;

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The following four changes are made to the Emergency Preparedness requirements for RHCs (continued)

- *Training:* Decreasing the training requirement from annually to every two years.
- *Testing:* Decreased the requirement for RHCs to conduct two testing exercises to one testing exercise annually.

- *Contact:* Kristin Shifflett, 410-786-4133, Ronisha Blackstone, 410-786-6882.

The Emergency Preparedness Regulations

P. EMERGENCY PREPAREDNESS REQUIREMENTS: REQUIREMENTS FOR EMERGENCY PLANS

- We are removing the requirements from our emergency preparedness rules for Medicare and Medicaid providers and suppliers that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts.

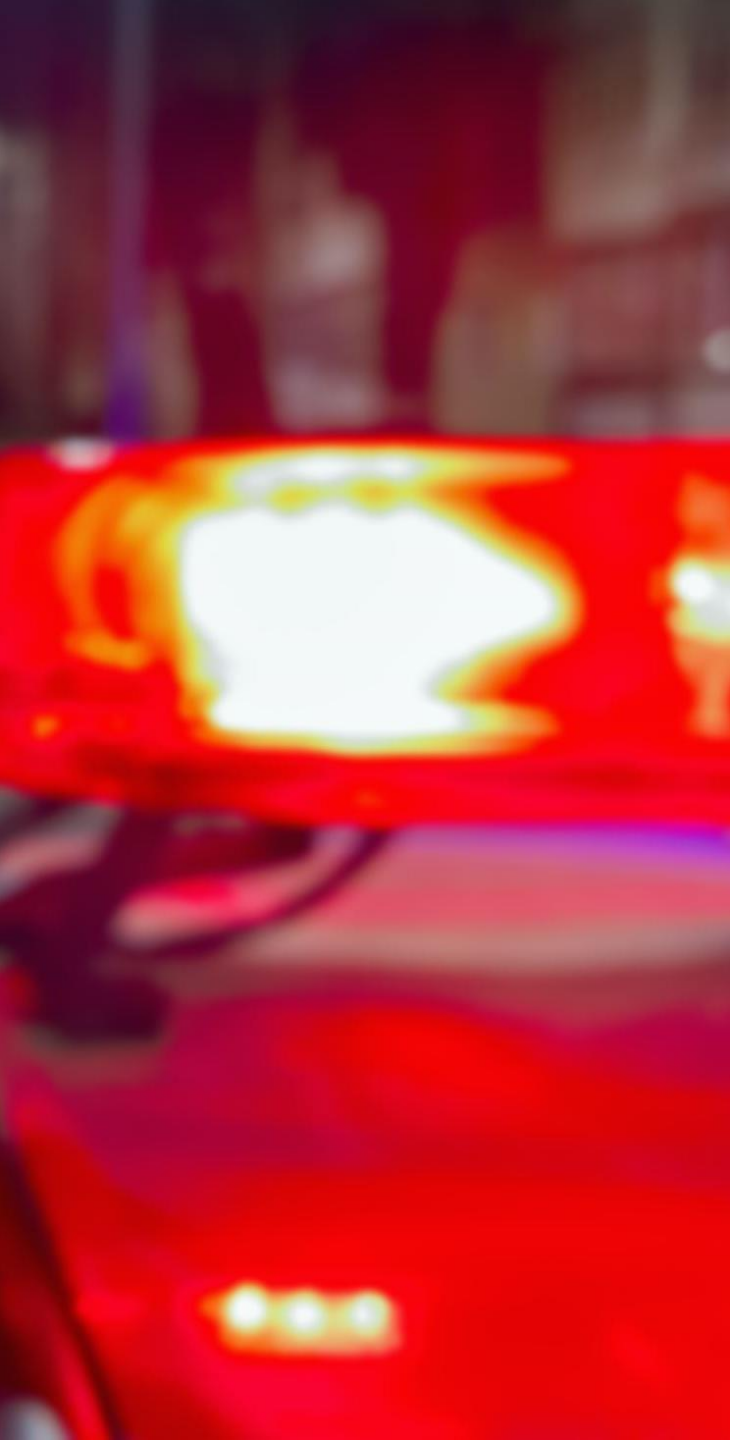
RHCs are still required to work with local EMA officials

- *Response:* We would like to point out that providers would still be required at the respective emergency preparedness requirements for each provider and supplier to include a process for collaboration/cooperation with officials; however, they would not be required to document efforts to contact these officials. **Therefore, this maintains the existence of a process for collaboration with officials without posing additional documentation burdens.** Therefore, we are finalizing this requirement as proposed and eliminating the documentation requirement for collaboration with emergency preparedness officials.

The Emergency Preparedness Regulations

- **Q. EMERGENCY PREPAREDNESS REQUIREMENTS: REQUIREMENTS FOR ANNUAL REVIEW OF EMERGENCY PROGRAM**

- **We are revising this requirement so that applicable providers and suppliers review their Emergency program biennially, except for Long Term Care facilities, which will still be required to review their emergency program annually.**



The Emergency Preparedness Regulations

- **R. EMERGENCY PREPAREDNESS REQUIREMENTS: REQUIREMENTS FOR TRAINING**

- **We are revising the requirement that facilities develop and maintain a training program based on the facility's emergency plan annually by requiring facilities to provide training biennially (every 2 years) after facilities conduct initial training for their emergency program, except for long term care facilities which will still be required to provide training annually. In addition, we are requiring additional training when the emergency plan is significantly updated.**

Louisiana Will continue to require annual review of the EP Plans

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY
SECRETARY

State of Louisiana
Department of Health and Hospitals
Office of the Secretary

October 8, 2019

To: ESF8 Response Network

From: Cecile Castello, RN
Deputy Assistant Secretary
Health Standards Section

Subject: CMS Rule Changes

The recently released CMS rules issued September 30, 2019 relaxes the frequency of updating Emergency Preparedness plans from annually to every 2 years. Please note that LDH Health Standards' rules have not changed regarding Emergency Preparedness for annual update of the plan, the annual update of supporting components, the requirement for annual community exercises, as well as annual self-attestations for readiness as part of the annual license renewal application process

The location, scope and scale of any disaster is hard to predict. Annually updated plans, annually updated policies and procedures, and (a minimum) of annual engagement with emergency preparedness officials - prior to a disaster event - ensures that all facilities are postured for no-notice disaster events.

The frequency of severe weather to our state has increased. The nature of disasters is changing with compelling scientific evidence and studies indicating that the frequency, scope and scale of disasters is influenced by a changing climate. The last 3 years alone have demonstrated 'catastrophic' levels of disasters; namely, August 2016 flood disrupted as many homes as Katrina 2005; 2017 had 4 storms of a Category 4 or higher; and recently, Hurricane Dorian 2019 had 178mph winds (which exceeded Category 5 defined storm). Annual update of a facility's Emergency Preparedness Plan driven by exercises and drills assures that a facilities are prepared at all times.

Preparedness and Recovery is heavily dependent upon medical infrastructure being fortified and resilient. Annual community-based exercises are intended to advance preparedness at the facility and community level.

Exercises and updating the emergency plan ensures outreach to parish, state, federal and other critical stakeholders. These requirements are intended to advance transparency, as well as ensure a unified, scalable and integrated response during a time of disaster.

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The Emergency Preparedness Regulations

- **S. EMERGENCY PREPAREDNESS REQUIREMENTS: REQUIREMENTS FOR TESTING**

- **For inpatient providers, we are expanding the types of acceptable testing exercises that may be conducted. For outpatient providers, we are revising the requirement such that only one testing exercise is required annually, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise, every other year and in the opposite years, these providers may choose the testing exercise of their choice.**

The Old Emergency Preparedness Testing Requirements

- Facilities are currently required to conduct exercises to test the emergency plan at least annually. The facility must conduct two emergency preparedness testing exercises every year. Specifically, facilities must:
- Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the facility experiences an actual natural or-man made emergency that requires activation of the emergency plan (including their communication plan and revision of the plan as needed), the facility is exempt from engaging in a community-based or individual, facility based full-scale exercise for 1 year following the onset of the actual event;
- Conduct an additional exercise that may include either a second full-scale exercise that is community-based or individual, facility-based or a tabletop exercise that includes a group discussion led by a facilitator.

Emergency Preparedness Testing for Inpatient Services (NOT RHC)

- For providers of inpatient services (inpatient hospice facilities, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care facilities (LTCFs), ICFs/IIDs, and CAHs), we proposed to retain the existing requirement for these provider and supplier types to conduct two emergency preparedness testing exercises annually.
- **We proposed to expand the testing requirement options, such that one of the two annually required testing exercises could be an exercise of their choice, which could include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that included a group discussion led by a facilitator.**

Emergency Preparedness Testing for Outpatient (RHC) Services

- For providers of outpatient services we proposed to require that providers of outpatient services conduct only one testing exercise per year.

- Furthermore, we proposed to require that these providers participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year.

- In the opposite years, we proposed to allow these providers to conduct the testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

In the Event of an Emergency

- We proposed to clarify the testing requirement exemption by noting that if a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event.

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To Count as an Emergency Preparedness Drill, you need an After-Action Report

[Exercise Name]

After-Action Report/Improvement Plan

[Date]

The After-Action Report/Improvement Plan (AAR/IP) aligns exercise objectives with preparedness doctrine to include the National Preparedness Goal and related frameworks and guidance. Exercise information required for preparedness reporting and trend analysis is included; users are encouraged to add additional sections as needed to support their own organizational needs.

Rev. April 2013
HSEEP-IP01

EXERCISE OVERVIEW

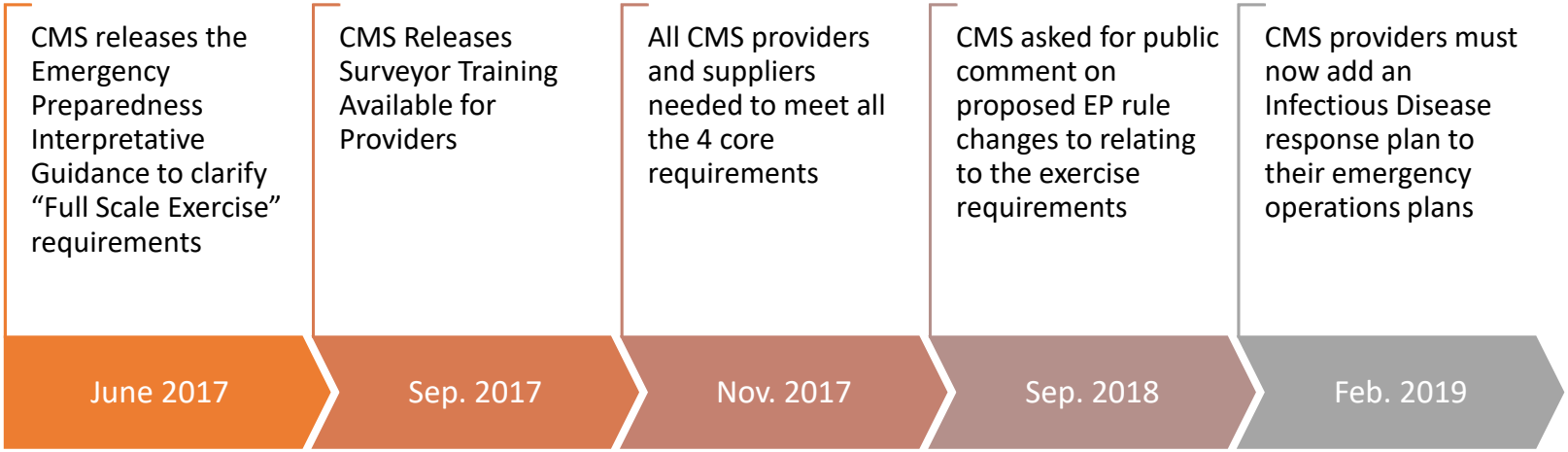
Exercise Name	[Insert the formal name of exercise, which should match the name in the document header]
Exercise Dates	[Indicate the start and end dates of the exercise]
Scope	This exercise is a [exercise type], planned for [exercise duration] at [exercise location]. Exercise play is limited to [exercise parameters].
Mission Area(s)	[Prevention, Protection, Mitigation, Response, and/or Recovery]
Core Capabilities	[List the core capabilities being exercised]
Objectives	[List exercise objectives]
Threat or Hazard	[List the threat or hazard (e.g. natural/hurricane, technological/radiological release)]
Scenario	[Insert a brief overview of the exercise scenario, including scenario impacts (2-3 sentences)]
Sponsor	[Insert the name of the sponsor organization, as well as any grant programs being utilized, if applicable]
Participating Organizations	[Insert a brief summary of the total number of participants and participation level (i.e., Federal, State, local, Tribal, non-governmental organizations (NGOs), and/or international agencies). Consider including the full list of participating agencies in Appendix B. Delete Appendix B if not required.]
Point of Contact	[Insert the name, title, agency, address, phone number, and email address of the primary exercise POC (e.g., exercise director or exercise sponsor)]

How much does the Emergency Preparedness rules save annually

- *RHCs/FQHCs:* **Combined total savings of $4,284,104** (((4 hours for an administrator at $107 per hour plus 4 hours for a registered nurse at $71 per hour) × 4,160 RHCs × 50 percent) $1,480,960+ (4 hours for an administrator at $107 per hour plus 4 hours for a registered nurse at $71 per hour) × 7,874 FQHCs × 50 percent) 2,803,144.

Appendix Z Updated in Feburary, 2019

CMS EP Rule Updates Since 2017



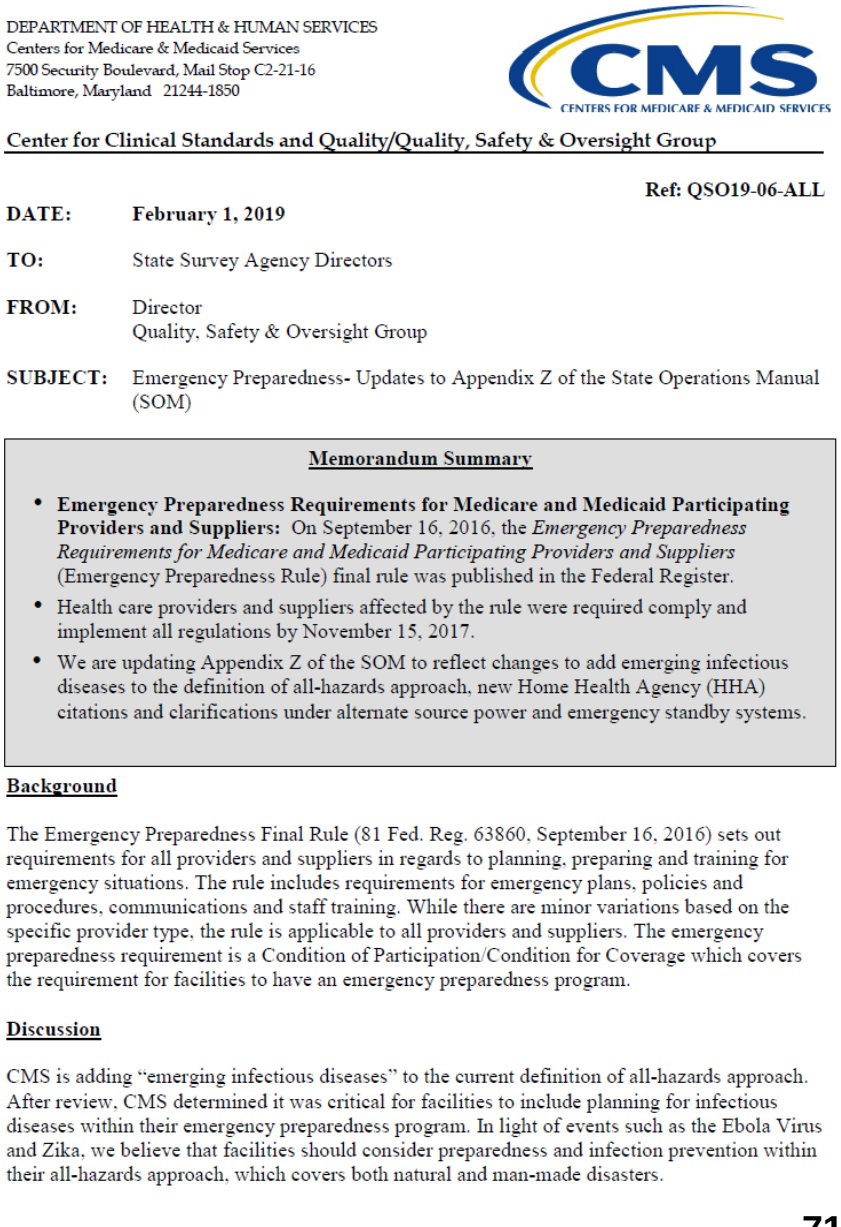
Appendix Z Revised on 2/1/2019

- **Appendix Z updated as of 2/1/2019. The red italics show the changes made with this revision (see downloads section). For the full Appendix Z, please see**
- **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf**

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-06-ALL.pdf

Revisions and Updates to Appendix Z

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-06-ALL.pdf



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO19-06-ALL

DATE: **February 1, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Emergency Preparedness- Updates to Appendix Z of the State Operations Manual (SOM)

Memorandum Summary

- **Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers:** On September 16, 2016, the *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (Emergency Preparedness Rule) final rule was published in the Federal Register.
- Health care providers and suppliers affected by the rule were required comply and implement all regulations by November 15, 2017.
- We are updating Appendix Z of the SOM to reflect changes to add emerging infectious diseases to the definition of all-hazards approach, new Home Health Agency (HHA) citations and clarifications under alternate source power and emergency standby systems.

Background

The Emergency Preparedness Final Rule (81 Fed. Reg. 63860, September 16, 2016) sets out requirements for all providers and suppliers in regards to planning, preparing and training for emergency situations. The rule includes requirements for emergency plans, policies and procedures, communications and staff training. While there are minor variations based on the specific provider type, the rule is applicable to all providers and suppliers. The emergency preparedness requirement is a Condition of Participation/Condition for Coverage which covers the requirement for facilities to have an emergency preparedness program.

Discussion

CMS is adding "emerging infectious diseases" to the current definition of all-hazards approach. After review, CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program. In light of events such as the Ebola Virus and Zika, we believe that facilities should consider preparedness and infection prevention within their all-hazards approach, which covers both natural and man-made disasters.

Include Infectious Diseases in All Hazards Risk Assessment & Develop a Policy

- **CMS is adding "emerging infectious diseases" to the current definition of all-hazards approach. After review, CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program. In light of events such as the Ebola Virus and Zika, we believe that facilities should consider preparedness and infection prevention within their all-hazards approach, which covers both natural and man-made disasters.**
- **http://www.ruralhealthclinic.com/s/2019-Master-Infectious-Disease-Policy-E50-to-add-to-the-Emergency-Preparedness-Policy-and-Procedure.docx**
- **http://www.ruralhealthclinic.com/s/2019-Emergency-Preparedness-Forms-Infectious-Disease-Forms.pdf**

CMS Relaxes Policy on Emergency Drugs and Biologicals for RHCs

NARHC is happy to report that CMS is significantly altering their guidance policy regarding emergency drugs and biologicals required in Rural Health Clinics. This change is effective immediately.

Previously, RHCs were required to stock drugs and biologicals from each of the following categories: 1-Analgesics; 2-Local Anesthetics; 3-Antibiotics; 4-Anticonvulsants; and 5-Antidotes, emetics, serums & toxoids. **However, as of September 3rd, 2019, RHCs will only be required to consider each category when they craft their written policies.** This means that RHCs will not be required to stock snake antidote, emetics, or anticonvulsants!

https://www.web.narhc.org/News/28058/CMS-Relaxes-Policy-on-Emergency-Drugs-and-Biologicals-for-RHCs

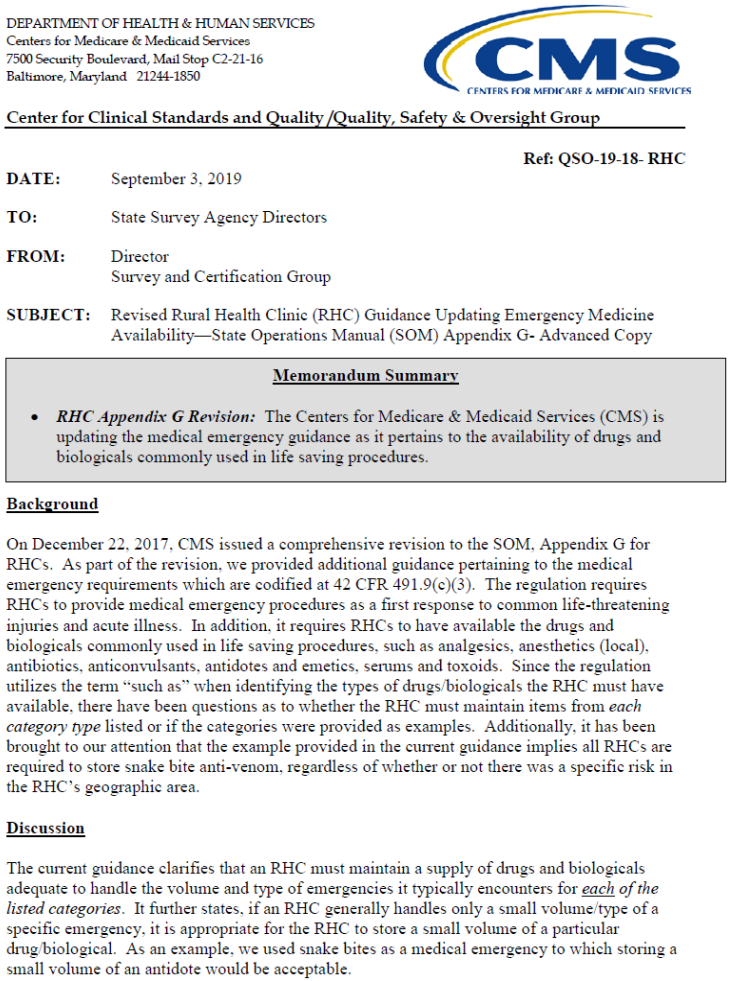
Appendix G - Emergency Drugs and Biologicals for RHCs

- *"While each category of drugs and biologicals must be considered, all are not required to be stored…*

- We will still be required to store drugs and biologicals for emergencies, but now, CMS is allowing us to determine which drugs and biologicals are most appropriate for our communities:

- *…when determining which drugs and biologicals it has available for purposes of addressing common life-threatening injuries and acute illnesses,* ***the RHC should consider, among other things, the community history, the medical history of its patients and accepted standards of practice. The clinic should have written policies and procedures*** *for determining what drug/biologicals are stored and that address the process for determining which drugs/biologicals to store, including identifying who is responsible for making this determination."*

Appendix G – Revision Dated September 3, 2019



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Quality, Safety & Oversight Group

Ref: QSO-19-18- RHC

DATE: September 3, 2019

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Rural Health Clinic (RHC) Guidance Updating Emergency Medicine Availability—State Operations Manual (SOM) Appendix G- Advanced Copy

Memorandum Summary

- ***RHC Appendix G Revision:*** The Centers for Medicare & Medicaid Services (CMS) is updating the medical emergency guidance as it pertains to the availability of drugs and biologicals commonly used in life saving procedures.

Background

On December 22, 2017, CMS issued a comprehensive revision to the SOM, Appendix G for RHCs. As part of the revision, we provided additional guidance pertaining to the medical emergency requirements which are codified at 42 CFR 491.9(c)(3). The regulation requires RHCs to provide medical emergency procedures as a first response to common life-threatening injuries and acute illness. In addition, it requires RHCs to have available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids. Since the regulation utilizes the term "such as" when identifying the types of drugs/biologicals the RHC must have available, there have been questions as to whether the RHC must maintain items from *each category type* listed or if the categories were provided as examples. Additionally, it has been brought to our attention that the example provided in the current guidance implies all RHCs are required to store snake bite anti-venom, regardless of whether or not there was a specific risk in the RHC's geographic area.

Discussion

The current guidance clarifies that an RHC must maintain a supply of drugs and biologicals adequate to handle the volume and type of emergencies it typically encounters for *each of the listed categories*. It further states, if an RHC generally handles only a small volume/type of a specific emergency, it is appropriate for the RHC to store a small volume of a particular drug/biological. As an example, we used snake bites as a medical emergency to which storing a small volume of an antidote would be acceptable.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-18-RHC.pdf

RHCs are required to disclose ownership, medical direction & Principal Direction and Operation in the Lobby

Dunder Mifflin Medical Associates

Ownership

Dunder Mifflin Medical Associates

100 Main Street

Scranton, Pennsylvania

Medical Direction

Marcus Welby, MD

Principal Direction and Operation

Michael Scott

http://www.ruralhealthclinic.com/s/2019-Certification-Master-Signage-with-Ownership-Medical-Direction-and-management-to-be-placed-in-lo.docx

Medicare Provider-Supplier Enrollment

- DMEPOS Enrollment
- Provider-Supplier Enrollment Contacts
- Enrollment Applications
- Internet-based PECOS
- **Medicare Application Fee**
- Ordering & Referring Information
- National Site Visit Contractor
- Opt Out Affidavits
- Preclusion List
- Provider Enrollment Moratorium
- Provider Enrollment Events
- Provider Enrollment Regulation
- Revalidations
- Taxonomy

Medicare Application Fee

Medicare Application Fee

Section 6401(a) of the Affordable Care Act (ACA) requires the Secretary to impose a fee on each "institutional provider of medical or other items or services and suppliers." The fee is to be used by the Secretary to cover the cost of program integrity efforts including the cost of screening associated with provider enrollment processes, including those under section 1866(j) and section 1128J of the Social Security Act. Based upon provisions of the ACA this fee will vary from year-to-year based on adjustments made pursuant to the Consumer Price Index for Urban Areas (CPI-U). The application fee is to be imposed on institutional providers that are newly-enrolling, re-enrolling/re-validating, or adding a new practice location - for applications received on and after March 25, 2011. The new application fee for CY 2020 is $595.

CMS has defined "institutional provider" to mean any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (except physician and non-physician practitioner organizations), or CMS-855S or associated Internet-based PECOS enrollment application.

You can review this matrix (PDF) to outline which actions will trigger the CMS application fee requirement by provider/supplier type.

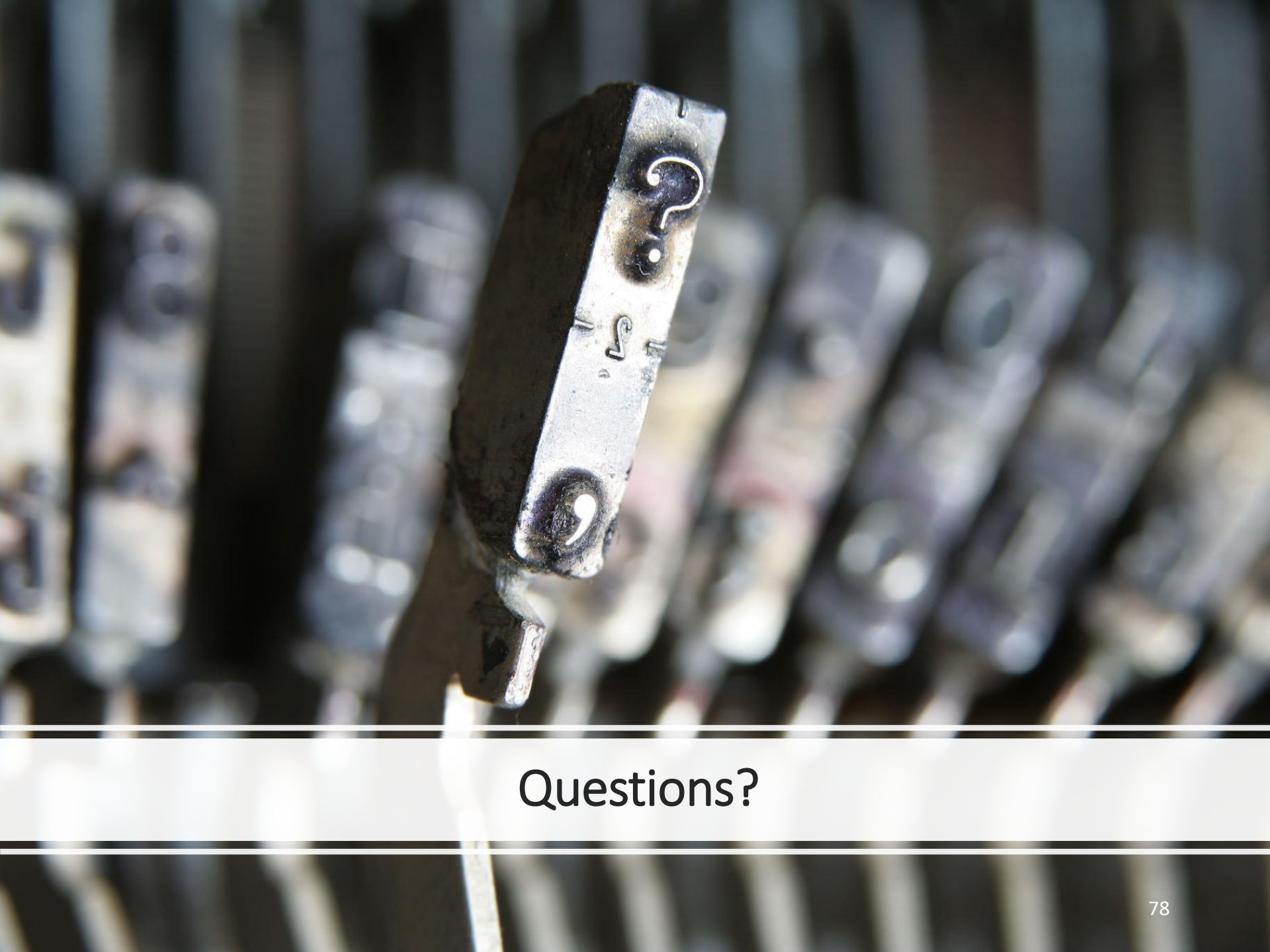
Use the link located in the 'Related Links Inside CMS' section below in order to pay the provider/supplier Medicare Enrollment Application Fee.

Downloads

SE1130 (PDF)

Related Links

Click Here to Pay Medicare Application Fee



Questions?