RHC Telehealth Billing and Coding May 21, 2020

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Presentation Objectives

- ✓ RHC Distant Site Rules: SE20016
- ✓ G2025 Claim Examples
- ✓ Service Detail Capture
- ✓ Telehealth Documentation
- ✓ HIPAA Considerations
- CS Modifier/Patient Consent
- ✓ Questions

SE20016 Revised: RHC Distant Site Services

CMS released NEW GUIDANCE on April 30, 2020, revising what was released on 4.17.2020.

Telephone only visits are now payable at \$92.03!! Please read on.

Section 3704 of the CARES Act authorizes RHCs and FQHCs to furnish distant site telehealth services to Medicare beneficiaries during the COVID-19 PHE.

Payment to RHCs and FQHCs for distant site telehealth services is set at \$92.03, which is the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS.

Because these changes in policy were made on an emergency basis, CMS needs to implement changes to claims processing systems in several stages.

Distant site telehealth services can be furnished by *any health care practitioner* working for the RHC or the FQHC within their scope of practice. (This includes 99201 and 99211.)

Practitioners can furnish distant site telehealth services from any location, including their home, during the time that they are working for the RHC or FQHC, and can furnish any telehealth service that is approved as a distant site telehealth service under the Physician Fee Schedule (PFS)!!

https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes RHCs and FQHCs must use HCPCS code G2025, the new RHC/FQHC specific G code for distant site telehealth services, to identify services that were furnished via telehealth beginning on January 27, 2020, the date the COVID-19 PHE became effective.

Changes in *eligible originating site locations*, including the patient's home during the COVID-19 PHE *are effective beginning March 6, 2020*.

RHC Telehealth Distant Site Services: furnished between January 27, 2020, and June 30, 2020

For telehealth distant site services furnished between January 27, 2020, and June 30, 2020:

- ✓ RHCs must report HCPCS code G2025 on their claims with the CG modifier.
- ✓ Modifier "95" (Rendered via Real-Time Interactive Audio and Video) may also be appended but is not required.
- ✓ These claims will be paid at the RHC's all-inclusive rate (AIR), and automatically reprocessed beginning on July 1, 2020, at the \$92.03 rate.
- ✓ RHCs do not need to resubmit these claims for the payment adjustment.

During the COVID-19 PHE, RHCs and FQHCs can furnish any telehealth service that is approved as a Medicare Telehealth Service under the PFS. (See <u>Medicare</u> <u>Approved Telehealth Services</u>)

Effective March 1, 2020, these services include CPT codes 99441, 99442, and 99443, which are audio-only telephone evaluation and management (E/M) services. RHCs and FQHCs can furnish and bill for these services using HCPCS code G2025.

We can adjust telephone only claims that were billed G0071 to G2025 to be paid the higher rate – back to March 1, 2020.

RHCs and FQHCs *can* furnish and bill for these services using HCPCS code G2025. To bill for these services:

- ✓ at least 5 minutes of telephone E/M service by a physician or other qualified health care professional who may report E/M services must be provided to an established patient, parent, or guardian.
- ✓ These services cannot be billed if they originate from a related E/M service provided within the previous 7 days or lead to an E/M service or procedure within the next 24 hours or soonest available appointment.

RHC Telehealth Distant Site Services: furnished between January 27, 2020, and June 30, 2020

FL42	FL43	FL44	FL45	FL46	FL47	
Rev CD	Desc	HCPCS/CPT	DOS	Units	Total C	Charge
0521	RHC Distant Site	G2025CG95CS	4/1/2020	1	\$	94.00
0001	Total Charge				\$	94.00

Through June 30, 2020:

- ✓ RHCs must report HCPCS code G2025 on their claims with the CG modifier.
- Modifier "95" (Real-Time Interactive Audio and Video) may also be appended but is not required.
- ✓ This will pay at the AIR.
- ✓ MAC will reprocess the claim to reconcile AIR payments to \$92.03.

RHC Telehealth Distant Site Services: Beginning July 1, 2020

FL42	2	FL43	FL44	FL45	FL46	FL47
Rev	CD	Desc	HCPCS/CPT	DOS	Units	Total Charge
	0521	RHC Distant Site	G2025CS95	7/1/2020) 1	l \$94.00
	0001	Total Charges				\$94.00

Beginning July 1, 2020:

- ✓ RHCs should no longer report the CG modifier.
- ✓ CS is ONLY for COVID related services.
- ✓ These claims will be paid at the \$92.03 rate.
- Medicare WILL apply cost-sharing (co-insurance and deductible) to Telehealth services.

G2025: MAC Processing

- MACs (Novitas, WPS, NGS, Noridian, Palmetto) loaded G2025 on varying dates.
- Clearinghouses (Trizetto, Zirmed, Availity) loaded G2025 on varying dates.

Each system and clearinghouse functions differently. How each of us handle coding for RHC claims will depend on the billing system and clearinghouse in use.

Patient Consent: Beneficiary consent is required for all services, including non-face-to-face services.

For RHCs and FQHCs, beneficiary consent to receive these services may be obtained by auxiliary personnel under general supervision of the RHC or FQHC practitioner; and the person obtaining consent can be an employee, independent contractor, or leased employee of the RHC or FQHC practitioner.

(see: https://www.cms.gov/files/document/covid-final-ifc.pdf).

"Currently, Medicare policy allows for the billing of the AWV (G0438-G0439) when delivered via telehealth provided that all elements of the AWV are provided (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AWV Chart ICN905706.pdf).

For the duration of the public health emergency, the AWV may be administered using audio-only technology, if a video connection with the patient is not possible. If the patient can self-report elements of the AWV (i.e., height. weight, blood pressure, other measurements deemed appropriate based on medical and family history), those measurements may be included and recorded in the medical record as reported by the patient. Guidance for when the patient cannot self-report is currently under review, and CMS plans to issue guidance soon."

COVID-19 Help Desk Team



- 1. No service detail for the *Medicare Coordination of Benefits* system to capture. Medicare will not "know" if an Annual Wellness or an E/M visit was performed.
- 2. How will Medicare know that this service was preventive and should not have co-insurance or deductible amounts applied.
- 3. How will our ACOs or other entities know that the RHC is meeting quality measures?
- 4. If provider compensation is based on RVUs (Relative Value Units). How would these services be captured on our cost report? How will that work?

The example below is a *suggestion*! (G0439 or other CPT detail should NOT go out on the claim). This method is only a suggested method of capturing service detail.

After July 1, 2020: No CG Modifier

FL42	FL43	FL44	FL45	FL46	FL47	
Rev CD	Desc	HCPCS/CPT	DOS	Units	Total	Charge
0521	RHC Distant Site	G202595	8/21/2020	1	\$	94.00
0521	AWV	G043895			(Suppressed)	
0001	Total Charge				\$	94.00

*These services MUST be removed from Cost Report calculations! This will inflate the patient count!

Repeat: This is a suggestion!! This is not a requirement.

- 1. G2025 MUST go out on the claim. NOT the detail.
- 2. *These services MUST be removed from Cost Report calculations! This will inflate the patient count and reduce your rate!
- 3. These are for reporting and tracking ONLY!

After July 1, 2020: No CG Modifier

FL42	FL43	FL44	FL45	FL46	FL47	
Rev CD	Desc	HCPCS/CPT	DOS	Units	Total	Charge
0521	RHC Distant Site	G202595	8/21/2020	1	\$	94.00
0521	AWV	G043895			(Suppressed)	
0001	Total Charge				\$	94.00

CS Modifier for COVID-Related Services: Co-Insurance MUST be Waived

- ✓ For services related to COVID-19 testing, including telehealth, RHCs and FQHCs must waive the collection of co-insurance from beneficiaries.
- ✓ For COVID-related services in which the coinsurance is waived, RHCs and FQHCs must report the "CS" modifier on the service line.

RHCs can receive payment for Virtual Communication Services when at *least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC practitioner* to a patient who has had an RHC billable visit within the previous year.

- The medical discussion or remote evaluation is for a condition not related to an RHC service provided within the previous 7 days, and -
- ✓ The medical discussion or remote evaluation *does not lead* to an RHC visit within the next 24 hours or at the soonest available appointment.

G0071: Virtual Check-In

Virtual Check-In (Brief Communication Technology-based Service):

- Performed by a physician or other qualified health care professional;
- ✓ Revenue Code: 0521
- ✓ COVID-19: Available to ALL patients, including new patients, effective 3.17.2020.
- ✓ not originating from a related E/M service provided within the previous 7 days;
- ✓ nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment;
- ✓ 5-10 minutes of medical discussion.
- ✓ Text and email count.

G0071 FAQ: Types of Communication

Virtual communication services would be initiated by the patient contacting the RHC or FQHC by:

- ✓ a telephone call;
- ✓ integrated audio/video system;

 ✓ a store-and-forward method such as sending a picture or video to the RHC or FQHC practitioner for evaluation and follow up within 24 hours.

The RHC or FQHC practitioner may respond to the patient's concern by telephone, audio/video, secure text messaging, email, or use of a patient portal.

E-Visits, the patient must generate the initial inquiry and communications can occur over a 7-day period. **RHCs bill these using G0071**

The services may be billed using CPT codes 99421-99423 as applicable. The patient must verbally consent to receive virtual check-in services. The Medicare coinsurance and deductible would apply to these services.

✓ Patient Consent can be obtained by the staff, verbally.

✓ Providers can waive cost-sharing for all telehealth services and visits.

G0071 (Virtual Communication Services) is billed either alone or with other payable services.

Payment for G0071 is temporarily (during PHE) set at the PFS national average of the non-facility average for G2010, G2012, 99421, 99422, and 99423.

For 2020, the payment amount for code G0071 will be \$24.76.

Virtual Check-In RHC Claim Example

Rev CD	Desc	HCPCS/CPT	DOS	Units	Total Charge	
0521	Virtual Check-In	G0071CS	4/2/2020	1	\$	24.76
0001	Total Charge				\$	24.76

- ✓ Do NOT report with CG.
- ✓ G0071 is for RHCs only.
- ✓ We do not bill G2010 OR G2012.
- ✓ Virtual Check-In G0071 encompasses Remote Check-In AND Remote Evaluation.
- ✓ Use modifier CS to waive co-ins/ded ONLY IF COVID-related.
- ✓ MACs will automatically reprocess any claims with G0071 for services furnished on or after March 1, 2020 that were paid before the claims processing system was updated.

General Rule: If the MA plan is paying the AIR, it will typically follow RHC reimbursement rules.

If the MA plan is NOT paying the AIR (i.e. paying as fee-forservice), it will typically follow Medicare Fee-for-Service rules.

Commercial Insurance

- Commercial Insurance each have their own requirements as well.
- ✓ Most of these follow Medicare Part B FFS rules.
- ✓ NOT what RHCs are required to do.
- ✓ Please confirm their policies and reimbursement provision.

Medicaid plans are state specific with variation among plans with HCPCS codes, modifiers and whether telephone visits are allowed.



Documentation of Telehealth Services Key Points Telemedici Notes

- Documentation should support the type of service and level of service.
- Working With or Around your PM/EHR
- Stop and Start Times
- Verbal Consent and Acknowledgment By Patient that they understand the provider may be using a non-compliant communication method which may not be secure.
- Prompt completion of records. Recommendation is 48 hours. Some states and medical boards have their own regulations. More important to be timely with telehealth.

MGMA Best Practices

Documentation requirements for a telehealth service are the same as for a face-to-face encounter. The information of the visit, the history, review of systems, consultative notes or any information used to make a medical decision about the patient should be documented. Best practice suggests that documentation should also include a statement that the service was provided through telehealth, both the location of the patient and the provider and the names and roles of any other persons participating in the telehealth service.

It is advisable to follow local Medicare Administrative Contractor (MAC) guidance for final instructions on billing and documentation requirements for telehealth services. Additionally, private payers may follow the guidelines set forth by Medicare or may have their own.

<u>https://www.mgma.com/resources/financial-</u> <u>management/navigating-telehealth-billing-</u> <u>requirements</u>

AHIMA GUIDELINES

- 1. The telemedicine provider must assess the patient's need for telemedicine services/orders through an identification assessment process. (Is a telemedicine service necessary or appropriate?)
- 2. Once the need is confirmed a telemedicine appointment can be scheduled and executed. (When will the telemedicine service happen and how?)
- 3. The telemedicine provider is responsible for accurately documenting all required content during the telemedicine encounter.
- 4. The telemedicine provider completes the telemedicine encounter and will review telemedicine orders.
- 5. The telemedicine provider will incorporate telemedicine orders into the treatment plan.
- 6. Documentation of all steps and follow-up is required.

More AHIMA Guidelines

At a minimum, AHI MA recommends that each telemedicine record contain the following:

- Patient name
- Identification number
- Date of service
- Referring physician
- Consulting physician
- Provider organization
- Provider location
- Patient location
- Telemedicine order
- Type of evaluation performed

• Informed consent, if appropriate.

• Evaluation results (In many telemedicine programs, the consulting physician/organization retains the original and a copy is sent to the referring physician/organization)

- Diagnosis/impression
- Recommendations for further treatment

RECORD CONTENT

<u>Telemedicine records should be kept in the same</u> <u>manner as other health records</u>.

The specific documentation needs vary depending upon the level of telemedicine interaction. The organization using telemedicine information to make a decision on the patient's treatment must comply with all standards, including the need for assessment, informed consent, documentation of event (regardless of the media), and authentication of record entries.

https://healthsectorcouncil.org/wp-content/uploads/2018/08/AHIMA-Telemedicine-Toolkit.pdf • Patient Demographics/Type of Service

TEL	.EN	IEDI	CINE/	TELE	EPHO	NIC	NOTE
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□ Claim Date _____
□ Scanned to EHR by _____

Date: Provider Name:	Provider Credential:						
Pt Name:	DOB/Age	Start Time:	Stop Time:				
Minor: Parent/Guardian is present.							
Account/Med Record #		New Pt	Established Pt				
HIPAA Acknowledged Verbal Co	onsent Obtained	1 By					
Type of Service: 🛛 Audio/Visual Live	e 🗆 Audio/Visua	al Stored 🛛 Audio 🤇	Only 🛯 Phone Call				
□ Virtual Communication Service □	No Pt Devise/	Computer App Use	d:				

PURPOSE OF TELEMEDICINE/TELEHEALTH SERVICE:

Possible Exposure to COVID-19	Symptoms of COVID-19	Other Respiratory S/S
Other Acute Condition	Other Chro	nic Condition
Other:		Care Management
Location of Patient:	Location of Provide	er:

Status of Chronic Conditions as HPI

HISTORY OF PRESENT ILLNESS or Rea	ason for Telem	edicine/Telehe	alth Visit	
Signs and Symptoms: Cough Fev	er	Body Aches	Sinus Congestion	
Chest Congestion E Fatigue/Malaise	Nausea	Diarrhea	Headache SOB	
Other Acute Signs/Symptoms:			COVID Exposure	
ONSET/ Exposure Date:				
Travel History Self/Family/Others:				
Status of Chronic Conditions: 1.			Stable Worse Better	
2 Stable 🗆 Wo			Stable □ Worse □ Bette	r
□ Problem List Reviewed □ Medicat <u>Review of Systems</u> : Experiencing Any O If yes, which body system and complaint:	ther Complaints			
Vitele nev Dt/llisterien: 🗆 Temm				
Vitals per Pt/Historian:			□BP	
Observation/Visualization:				

Assessment and Plan

C Record Sent
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e:

Virtual Communication Services

- Goo71 is still a valid code.
- Goo71 is not going away.
- Reimbursement During PHE is \$24.75
- Reimbursement will revert back to original amount after PHE.
- Still used to report services that are technology assisted services such as e-check ins and e-visits. (secure text, patient portal, brief calls with provider to determine if other service is needed.)

nQuiseekuc RHC Medicare Bil	Iling Distant Site Telehealth ril 30, 2020
Virtual Communication Services	Telehealth Services Audio and Visual
Services that could be billed as: Virtual Communication Services Patient Portal Technology-Assisted <u>Code List:</u> G010 G012 99421 99422 99423	All Services on the CMS Approved Telehealth List* Use "normal" Codes No special telehealth codes <u>Examples:</u> Office E & M Ex: 99213 Behavioral Health Ex: 90832 Nursing Home Ex: 99307 Hospital IP Ex: 99222 Preventive Srvs Ex: G0439 TCM Ex: 99495 Any code on approved CMS list. 99441-99443 Audio Only reportable after 3/1/2020
Ļ	Ļ
Use G0071	January 27 thru June 30th G2025
No -CG or -95 Modifier ADD -CS if COVID Screening	Use -CG (95 is optional) Add -CS to waive coinsurance/COVID
\$24.75 During COVID/PHE	\$92.03 for all RHCs**
NO CHANGE IN CODE on 7/1/2020 Reimbursement Reverts Back to \$13.53 after COVID	USE G2025 with no -CG modifier (95 is optional) <u>after July 1, 2020.</u>
*https://www.cms.gov/Medicare/Medicare-Gene ** Will pay at AIR until July 1 st when claims will See MLN SE20016	

Tracking Services/Claims on Hold

Page____of_____

:0VI	D-19 PATI	ENT SER	VICE LOG			CUNIC NAME:										
	Patient Information					Type of Ser	rvice.			Action, Result, Outcome or Treatment						
•	Date	Patient Initials	Acct or MR #	Phone Prescreening by staff	Clink Encounter	Virtual Comm Service Dy Provider	Telemed Encounter Approved by Paver	Housecall by Provider	Seen in Other Setting	Flu Swap	1 MBP	Referred for terting		Quarantine /Isolate Self		Other
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_																
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HIPAA DURING COVID-19

- The OCR will exercise discretion in enforcement of violations when a provider has acted in good faith to provide telemedicine during the emergency.
- A covered health care provide may use audio or video communication technology to provide telehealth to patients during the emergency can use audio/video applications. (Examples: Facetime, Skype, Messenger) that would normally not be compliant as long as they are <u>not</u> public facing
- Under this Notice, however, Facebook Live, Twitch, TikTok, and similar video communication applications are public facing, and should not be used in the provision of telehealth by covered health care providers
- Applies to telehealth provided for any reason, regardless of <u>whether the telehealth</u> <u>service is related to the diagnosis and</u> <u>treatment of health conditions related to</u> <u>COVID-19.</u>

Other HIPAA Concerns

- Retraining staff on HIPAA privacy and security basics.
 - Need to Know Rule
 - Which Disclosures are allowed in emergencies
 - Public Health Agencies
 - Other Healthcare Provider for Continuity of Care
 - For Immediate Harm of Others/Law Enforcement
- Security of Computers and Connections when employees are working from home. Firewalls, virus projection, encryption.
- Privacy of PHI when working remotely. Unauthorized access by others.



How to Use the -CS Modifer

What is the – CS modifier?

CMS began using the –CS modifier over a decade ago. One previous use of it was to identify injuries or illness associated with the 2010 Gulf Oil Spill, believe it or not. Its use was to identify Medicare claims attributed to a specific event or circumstance.

The use of the –CS modifier in today's COVID-19 pandemic is to identify services in which the patient sought care because there was a concern over exposure to or infection by the virus. Why do we nee the –C Modifie Cost-sharing does not apply for COVID-19 testing-related services, which are medical visits that: are furnished between March 18, 2020 and the end of the Public Health Emergency (PHE) that: 1)result in an order for or administration of a COVID-19 test; 2)are related to furnishing or administering such a test or 3)to the evaluation of an individual for purposes of determining the need for such a test; and are in any of the following categories of HCPCS evaluation and management codes:

- Office and other outpatient services
- Hospital observation services
- Emergency department services
- Nursing facility services
- Domiciliary, rest home, or custodial care services
- Home services
- · Online digital evaluation and management services

What does the – CS Modifer Do?

• The –CS Modifier waives any patient responsibility when the Medicare patient seeks medical evaluation and management created by the COVID-19 Pandemic.

- It encourages patients to seek care without any cost share.
- Medicare will reimburse the RHC its full AIR encounter rate when the –CS is appended to an E & M service.
- There is no cost share or coinsurance on Medicare lab services so the –CS modifier is not applicable.

To whic Codes A the –CS Modifie Appendo Use the -CS modifier when reporting <u>an evaluation and</u> <u>management service (in person or via approved telehealth</u> <u>services) when the service</u> resulted in:

1. Determining if the patient needs to be tested for COVID. Based on exposure risk or presenting symptoms, the provider determines through an evaluation and management service that screening or testing is required. The service may or may not result in diagnostic testing if the purpose of the visit is expressly related to a concern over COVID-19.

2. When the patient is screened or tested in the clinic. Based on exposure risk or presenting symptoms, the provider determines through an evaluation and management service that the patient needs to be tested.

3. When an order is written for the patient to be screened or tested elsewhere. Based on exposure risk or presenting symptoms, the provider determines through an evaluation and management service that the patient needs to be tested.

4. When the patient is referred elsewhere for screening or testing as a result of an E & M service.

The -CS Modifier is <u>not</u> appended to the lab test code because there is no cost share for these services.

What about the -CS Modifier and Commercial Plans? The Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) amended the FFCRA to provide a broader range of diagnostic items and services that plans must cover *without any cost sharing requirements or prior authorization or other medical management requirements.*

- The -CS Modifier should be able to be appended to commercial claims.
- Follow coding and billing guidance from specific payers.

What Should th Note Say?

Clinical Documentation

Clinical documentation should support the evaluation and management service which was provided. It should also support the diagnosis or diagnoses reported. *The provider should clearly document that the reason for the visit was to evaluate the patient's need for COVID-19 screening or testing.*

The assessment and plan should support the provider's decision whether to perform screening/testing or not. The COVID-19 diagnosis should only be assigned when the documentation supports a positive result and a definitive diagnosis

ICD-10-CM Diagnostic Coding for COVID-19

ICD-CM Code	Code Description	Assign when	Sequencing		
Zo3.818	Encounter for observation for suspected exposure to other biological agents ruled out	There is a concern about a possible exposure to COVID- 19.	First-listed		
Z20.828	Contact with and suspected exposure to other viral communicable diseases.	The person with an exposure or suspected exposure either tests negative or the test results are unknown.	First-listed		
Z11.59	Encounter for screening for other viral diseases	When an asymptomatic patient is screened and either tests negative or the test results are unknown.	First-listed		

Positive COVID-19 Diagnosis

ICD-CM Code	Code Description	Assign when	Sequencing
U07.1	COVID-19	When there is a confirmed positive diagnosis documented by the provider. The patient may be symptomatic or asymptomatic. The provider must document that the patient has COVID-19. Do not use as a rule- out or suspected diagnosis.	First-listed Do not use a Z code above if the positive is confirmed; List any manifestations (respiratory infection, pneumonia or bronchitis for example) as secondary diagnoses.

ICD-CM Code	Code Description	Assign when	Sequencing
O98.5x	Other viral diseases complicating pregnancy, childbirth, and the puerperium.	When a patient during pregnancy, childbirth or the puerperium presents with positive confirmation of COVID-19.	The O98.5 code is first listed followed by U07.1 for COVID-19 and then by any manifestation codes.
Ro6.o2 S Breath		When a patient presents with respiratory symptoms but there is no definitive diagnosis (COVID or non-COVID).	First-listed when no screening or testing is performed; may be secondary to the testing Z codes for known or suspected exposure.

Optional Cost Share Waiving for Telehealth

Optional Waiving of Telehealth Co-Insurance

Under normal circumstances, providers cannot waive a Medicare patient's co-insurance amount for a service billed to the Medicare program. Discounts to Medicare patients are considered to be kickbacks because they offer Medicare services below the standard cost. However, during the Public Health Emergency, CMS is giving providers the flexibility to waive coinsurance for telehealth services. Providers are not required to waive the patient's cost share of coinsurance but can do so during COVID-19. If a provider chooses to waive the coinsurance, the provider does NOT receive the full allowable amount of reimbursement. The coinsurance amount is written off and the provider agrees to provide the service for a reduced 80% of the allowable reimbursement. Providers may want to create a new adjustment code for COVID write-offs of co-insurance.

The Office of the Inspector General has issued the following opinion concerning Telehealth and the Waiving of Co-insurance. Please read this document for more details on how to implement this option compliantly.

https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policytelehealth-2020.pdf What about billing COVID-19 Lab Testing? Does there need to be an order for COVID Testing? The Interim Final Rule can be found here.

<u>https://s3.amazonaws.com/public-</u> inspection.federalregister.gov/2020-09608.pdf

In part, it states this:

Given the critical importance of expanding COVID-19 testing to combat the pandemic and the heightened risk that the disease presents to <u>Medicare beneficiaries</u>, we are amending our regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law. Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, we are also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which we are removing the ordering requirements publicly available.

COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE Updated April 30, 2020

CPT/HCPCS Code	Laboratory Code Long Descriptor	Code Category			
	COVID-19 Related Codes				
U0001	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	COVID-19			
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC)	COVID-19			
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), 2 amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R				
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	COVID-19			
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	COVID-19			
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	COVID-19			
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	COVID-19			
	Influenza/RSV Related Codes				
87275	Infectious agent antigen detection by immunofluorescent technique; influenza B virus	Influenza/RSV			
87276	Infectious agent antigen detection by immunofluorescent technique; influenza A virus	Influenza/RSV			
87279	Infectious agent antigen detection by immunofluorescent technique; Parainfluenza virus, each type	Influenza/RSV			

CLIA WAIVED Point of Care Testing for COVID and QW Modifier

MLN 11765 : https://www.cms.gov/files/document/mm11765.pdf

This article informs you about the addition of the QW modifier to HCPCS code U0002 (2019-nCoV Coronavirus, SARS-CoV-2/2019nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC) and 87635 [Infectious agent detection by nucleic acid DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique]. Medicare will permit the use of codes U0002QW and 87635QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020. Make sure your billing staffs are aware of these changes.

Test Kit Manufacturers and Commercial Laboratories Table:

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Date EUA Issued ©	Manufacturer		Diagnostic (Letter of Authorization)				Authorized Setting(s) ¹ -		Authorization Documents ² \$	Other Documents/	
03/20/2020	Cepheid		Xpert Xpress SARS-CoV-2 test		Molecular		H, M	, w	HCP, Patients, IFU for Labs, IFU for Point-of- Care	Letter Granting EUA Amendment(s) (April 28, 2020)	
03/27/2020	Abbott Diagnostics Scarborough, Inc.		ID NOW COVID-19		Molecular		H, M	, w	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 21, 2020)	
03/23/2020	Mesa Biotech Inc.		Accula SARS-Cov-2 Test		Molecular		H, M	, w	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 30, 2020)	

CLIA WAIVED COVID TESTS

"W" denotes that the kit is approved for clinics with Waived Certificates. All approved kits and equipment including those only approved for H-complex labs and M-moderately complex labs can be found at:

https://www.fda.gov/medical-devices/emergencysituations-medical-devices/emergency-useauthorizations#covid19ivd Problems Already with some Point of Care EUA Testing

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test

For Immediate Release:

May 14, 2020

Español (/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-informa-al-publico-sobre-posibles-preocupaciones)

Today, the U.S. Food and Drug Administration is alerting the public to early data that suggest potential inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19. Specifically, the test may return false negative results.

"We are still evaluating the information about inaccurate results and are in direct communications with Abbott about this important issue. We will continue to study the data available and are working with the company to create additional mechanisms for studying the test. This test can still be used and can correctly identify many positive cases in minutes. Negative results may need to be confirmed with a high-sensitivity authorized molecular test," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

https://www.fda.gov/news-events/press-

announcements/coronavirus-covid-19-update-fda-informspublic-about-possible-accuracy-concerns-abbott-id-nowpoint Centers for Medicare and Medicaid Services. <u>MLN 20016 Revised</u>. "New and Expanded Flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) During the COVID-19 Public Health Emergency (PHE)". April 30, 2020.

Health and Human Services. "<u>HHS OIG Policy Statement on Practitioners</u> <u>That Reduce, Waive Amounts Owed by Beneficiaries for Telehealth</u> <u>Services During the COVID-19 Outbreak</u>." <u>https://oig.hhs.gov</u>. March 2020. Medicare Claims Processing Manual – Chapter 9 RHC/FQHC Coverage Issues <u>www.cms.gov/manuals/downloads/clm104c09.pdf</u>

Medicare Benefit Policy Manual – Chapter 13 RHC/FQHC <u>www.cms.gov/Regulations-and</u> <u>Guidance/Guidance/Manuals/Downloads/bp102c13.pdf</u>

Medicare Claims Processing Manual UB04 Completion <u>www.cms.gov/manuals/downloads/clm104c25.pdf</u>

Medicare Benefit Policy Manual- Chapter 15 Other Services www.cms.gov/Regulations-and Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

RHC - CMS Resources

Virtual Communication FAQ

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/Downloads/VCS-FAQs.pdf

State Operations Manual Appendix G (Updated 1.2.18)

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap g rhc.pdf

Provider-Based Rules (42 CFR 413.65)

https://www.law.cornell.edu/cfr/text/42/413.65