

TOP 10 QUESTIONS HEALTH CARE PROVIDERS NEED TO KNOW ABOUT LEGISLATION RELATED TO COVID-19

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INTRODUCTION

TOP 10 QUESTIONS

- What are a Part B provider's responsibilities in regard to the stimulus funds being received?
- 2. How have LCDs and NCDs been affected by COVID-19?
- 3. Can a health care provider use telehealth to take care of patients?
- 4. Which providers are allowed to order Medicaid items right now?
- 5. What are the payment issues providers should understand?

- 6. What documentation changes have taken place for suppliers?
- 7. Are there other regulatory areas that have been affected by the PHE?
- 8. What are the federal government, states, and PBMs doing to lessen the burden on pharmacies during the pandemic?
- 9. What are key COVID-19 employment laws affecting health care providers?
- 10. What are the top 5 tips for employers during this pandemic?



ACRONYMS

- PHE Public health emergency
- IFR/IFC CMS's Interim Final Rule, focused on COVID-19
- CARES Act Coronavirus Aid, Relief, and Economic Security Act (phase 3 stimulus)
- LCD DME MAC local coverage determination
- NCD CMS national coverage determination
- F2F Face-to-Face encounter requirement
- FFS Fee for service
- SWO Standard Written Order



CMS GUIDANCE/RULES

- On March 30, CMS released 3 new documents providing significant new guidance to facilitate the provision of DMEPOS during the COVID-19 PHE.
 - IFR effective March 1, 2020 (published April 6, 2020) https://www.cms.gov/files/document/covid-final-ifc.pdf
 - DMEPOS: CMS Flexibilities to Fight COVID-19
 https://www.cms.gov/files/document/covid-dme.pdf
 - COVID-19 Provider Burden Relief FAQ
 https://www.cms.gov/files/document/provider-burden-relief-faqs.pdf





QUESTION #1

What are a Part B provider's responsibilities in regard to the stimulus funds being received?

STIMULUS FUNDS

- CARES Act to provide \$30 billion of a \$100 billion fund to Medicare suppliers and providers to assist with expenses incurred and revenue lost due to COVID-19.
- Providers and suppliers that received Medicare fee-for-service reimbursements in 2019 are eligible to receive payments.
- Providers and suppliers have begun to see these funds being deposited into their bank accounts.
- Providers and suppliers who receive the funds will have 30 days to sign a certification that they are entitled to receive the funds and that they are not currently excluded from participation in the Medicare or Medicaid program.
- Certification information can be found at <u>www.hhs.gov/sites/default/files/relief-fund-payment-terms-and-conditions-04132020.pdf</u>.





QUESTION #2

How have LCDs and NCDs been affected by COVID-19?

LCD/NCD SUSPENSION

- CMS Interim Final Rule
 - During the PHE, CMS will not enforce the NCD and LCD clinical indications for coverage for respiratory, home anticoagulation management, and infusion pumps.
 - CMS is providing "maximum flexibility" for practitioners to care for their patients.
 - IFR supercedes all other sub-regulatory requirements
 - If the same requirement exists in another Medicare or DME MAC publication, then the IFR supercedes
 - E.g., Medicare Program Integrity Manual



LCD/NCD SUSPENSION

- LCD/NCD Suspension includes, but is not limited to:
 - NCD 240.2 Home Oxygen
 - NCD 240.4 CPAP for OSA
 - LCD L33800 Respiratory Assist Devices
 - NCD 240.5 Intrapulmonary Percussive Ventilator
 - NCD 190.11 Home Prothrombin Time/International Normalized Ration for Monitoring Anticoagulation Management
 - NCD 280.14 Infusion Pumps
 - LCD L33794 External Infusion Pumps



LCD/NCD SUSPENSION

- Oxygen
 - Will short-term oxygen be covered for beneficiaries diagnosed with COVID-19?
 - Yes. CMS is exercising enforcement discretion to cover medically necessary home use of oxygen for patients diagnosed with COVID-19 during the emergency.
 - https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
 - Are there special billing requirements?
 - Additional information will be provided by the DME MACs.





QUESTION #3

Can a health care provider use telehealth to take care of patients?

- 1135 Waiver Information
 - Clinical indications for coverage suspended during Coronavirus pandemic.
 - Allow seniors access to their practitioners while limiting exposure to spread of the coronavirus.
 - Removes restriction for use in rural areas only (temporarily).
 - Allows for use with beneficiary in their "home" (temporarily).
 - Allows for "common office visits" without regard to diagnosis.
 - Prevents unnecessarily entering health care facilities.



- Under the PHE, all beneficiaries across the country can receive telehealth and other communications technology-based services wherever they are located.
- Clinicians can provide these services to new or established patients.
- Physicians can waive Medicare copayments for these services.
- Broad range of clinicians can now provide certain services by telephone to their patients.
- To enable services to continue while lowering exposure risk, clinicians can now provide additional services by telehealth including emergency department visits.



- Virtual Services
 - Telehealth visits
 - Interactive audio and video
 - New or established patients
 - Virtual Check-ins
 - Telephone or video
 - New or established patients
 - E-Visits
 - Electronic communication via patient portal
 - New and established patients



PMD Evaluations

- F2F for PMD is required by statute.
- The statute has always allowed for telehealth visits for PMD F2F under previous limitations.
 - Must meet the requirements of 42 CFR §§ 410.78 and 414.65 for purposes of DMEPOS coverage.
- Expanded telehealth provisions now also apply to PMD F2F.

PTs/OTs

- Recently passed legislation only serves to ease access to existing telehealth services—it does
 not expand the definition of who can provide telehealth services.
- Currently, the statutory definition of a telehealth-eligible provider does not include occupational or physical therapists.



PMD Evaluations

- April 4, 2020, video from CMS regarding telehealth included link to a list of services now covered under telehealth. It included the following as "temporary addition for the PHE for the COVID-19 pandemic" but they did not add PT/OT to the list of telehealth-eligible providers.
 - 97161 PT eval low complex 20 min
 - 97162 PT eval mod complex 30 min
 - 97163 PT eval high complex 45 min
 - 97165 OT eval low complex 30 min
 - 97166 OT eval mod complex 45 min
 - 97167 OT eval high complex 60 min
 - 97755 Assistive Technology Assess



PMD Evaluations

- PT/OT via telehealth is not covered by Medicare but is covered by some Medicaid plans and commercial plans.
- Ultimately, the responsibility of determining whether telehealth is appropriate is up to the PT/OT; but, in order for the PMD to be covered by Medicare, it must meet the statutory definition of a telehealth which currently precludes telehealth.
- Objective measurements cannot be done via telehealth—still required per LCD.



PMD Evaluations

- Headline from APTA: "New CMS Rule Includes Therapy Codes in Telehealth, Stops Short of Allowing PTs to Conduct Telehealth Services"
- Temporary changes that give a nod to the potential for true telehealth by PTs even though regulatory barriers still prevent that from happening.
 - Could it be a sign of more to come?
- In the meantime, APTA advises members to assume that PTs are not recognized as telehealth providers by CMS.





QUESTION #4

Which providers are allowed to order Medicaid items right now?

MEDICAID ORDERING

- Allowing additional practitioners to order medical equipment and supplies under the Medicaid Home Health Benefit.
 - The IFR expands current regulations to allow additional practitioners within their scope of practice to order Medicaid home health services.
 - Includes physician assistants and nurse practitioners.
 - CARES Act provides permanent allowance, but CMS has 6 months to implement.
 - The IFR allows these practitioners to order as of March 1, 2020.



MEDICAID - ORDER EXPANSION

- DMEPOS Services are covered under the home health benefit for Medicaid.
- H.R.748 CARES Act
 - ... by a nurse practitioner, clinical nurse specialist, or physician assistant after a date specified by the Secretary in no case later than the date that is 6 months after the date of the enactment of the CARES Act.
- IFR
 - In recognition of the critical need to expand workforce capacity, we are amending 42 CFR §440.70 to allow licensed practitioners practicing within their scope of practice, such as, but not limited to, NPs and PAs, to order Medicaid home health services during the existence of the PHE for the COVID-19 pandemic.



MEDICAID - BIG DEAL?

- Many States have allowed a licensed practitioner to order within the scope of their practice.
- But...11 STATES ONLY ALLOWED PHYSICIANS
 - Arkansas, California, Louisiana, Maine, Michigan, Missouri, Mississippi, New Mexico, Pennsylvania, Texas, and Washington.
 - Some allowed some DMEPOS to be ordered by a PA or particular category.
- AAHomecare has worked for several years with NP and PA associations to have this change made.





QUESTION #5

What are the payment issues providers should understand?

CMS IFR

- Part B Advance Payments
 - Existing law allows a carrier to make a conditional partial payment in advance of processing a claim that it is unable to process within established time limits.
 - IFR allows partial payment if
 - MAC is unable to process the claim timely or is at risk of being untimely, or
 - The supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.
 - IFR permits payment of up to 100% of anticipated payment based on historical assigned claims data.



- Advance payments
 - To qualify for advance/accelerated payments the provider/supplier must
 - Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form,
 - Not be in bankruptcy,
 - Not be under active medical review or program integrity investigation, and
 - Not have any outstanding delinquent Medicare overpayments.



Advance payments

- Suppliers will be asked to request a specific amount using an Advance Payment Request form provided on each MAC's website.
- Most providers and suppliers will be able to request up to 100% of the Medicare payment amount for a 3-month period.
- Each MAC will work to review and issue payments within 7 calendar days of receiving the request.
- CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment.



- Advance payments
 - Suppliers will have 210 days from the date of the accelerated or advanced payment to repay the balance.
 - Suppliers can continue to submit claims as usual after receiving the advance payment.
 - Suppliers will receive full payments for their claims during the 120-day delay period.
 - At the end of the 120-day period, the recoupment process will begin; and every claim submitted by the supplier will be offset from the new claims to repay the advanced payment.



- Advance Payments during the COVID-19 PHE
 - Hotline numbers available for questions
 - Jurisdiction A: 866-575-4067
 - Hours of operation: Monday Friday, 8 am to 6 pm CDT
 - Jurisdiction B: 855-769-9920
 - Hours of operation: Monday Friday, 7 am to 4 pm CDT
 - Jurisdiction C: 855-769-9920
 - Hours of operation: Monday Friday, 7 am to 5 pm CDT
 - Jurisdiction D: 866-575-4067
 - Hours of operation: Monday Friday, 8 am to 6 pm CDT
 - Watch for updates on weekend hours



- Part B Drugs
 - Requests for prescription drug refills
 - DME MACs allowed to make payment for greater than 30-day supply
 - Immunosuppressive drugs, oral anticancer drugs, and intravenous immune globulin (IVIG)
 - Effective for all Part B drug dates of service on or after March 1, 2020
 - Append the CR modifier to the HCPCS code
 - Enter "COVID-19" in the claim narrative



Part B Drugs

- March 19, 2020, Medical Director Joint Article published
 - Billing of Part B drugs to DME MACs during COVID-19 pandemic dispensing amounts
 - Jurisdiction A: https://med.noridianmedicare.com/web/jadme/topics/emergencies-disasters
 - Jurisdiction B: https://www.cgsmedicare.com/jb/pubs/news/2020/03/cope16419.html
 - Jurisdiction C: https://www.cgsmedicare.com/jc/pubs/news/2020/03/cope16419.html
 - Jurisdiction D: https://med.noridianmedicare.com/web/jddme/topics/emergencies-disasters



- Fee Schedules in non-CBA non-Rural areas
 - CARES Law, enacted DATE
 - With respect to items and services furnished on or after the date that is 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall apply section 414.210(g)(9)(iv) of title 42, Code of Federal regulations (or any successor regulation), as if the reference to "dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section" were instead a reference to "dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount."



EXAMPLES OF FEE SCHEDULES FOR NON-CBA/NON-RURAL NEW ENGLAND AND SOUTHEAST REGIONS

HCPCS COL	HCPCS DESCRIPTION	2015 FEE SCHEDULE 🕶	AVG. RURAL RATE	EXPIRING 03/05/2020 AVG.NON- RURAL RATE	STARTING 03/06/2020 AVG. NON-RURAL RELIEF RATE	AVG. NON-RURAL RELIEF
E0260	HOSPITAL BED, SEMI ELECTRIC	\$134.38	\$103.55	\$57.76	\$76.91	33%
E0601	CPAP	\$96.24	\$72.89	\$40.37	\$54.34	35%
E1390	OXYGEN CONCENTRATOR	\$180.92	\$136.77	\$75.16	\$101.60	35%
K0001	MANUAL WHEELCHAIR STANDARD	\$56.58	\$42.06	\$20.02	\$29.16	46%
K0823	POWER WHEELCHAIR, GROUP 2 CAPTAINS CHAIR	\$577.42	\$451.89	\$260.41	\$339.66	30%
E0260	HOSPITAL BED, SEMI ELECTRIC	\$134.38	\$103.55	\$62.01	\$80.10	29%
E0601	CPAP	\$100.96	\$75.38	\$41.21	\$56.15	36%
E1390	OXYGEN CONCENTRATOR	\$180.92	\$136.77	\$75.74	\$102.04	35%
K0001	MANUAL WHEELCHAIR STANDARD	\$54.88	\$41.17	\$24.65	\$32.21	31%
K0823	POWER WHEELCHAIR, GROUP 2 CAPTAINS CHAIR	\$577.42	\$451.89	\$277.94	\$352.81	27%



SEQUESTRATION RELIEF MAY 1-DECEMBER 31, 2020 APPROXIMATELY \$138 MILLION

Product Category	2019 Allowed \$\$	2% Projected Increase	Additional Payment	Avg. Monthly Change	Projected 8 Month
VENTILATOR	\$503,538,118	\$513,608,881	\$10,070,762	\$839,230	\$6,713,842
OXYGEN	\$756,572,038	\$771,703,479	\$15,131,441	\$1,260,953	\$10,087,627
COMMODES/BED PANS/URINALS	\$11,843,550	\$12,080,421	\$236,871	\$19,739	\$157,914
CPAP/RAD	\$1,114,881,599	\$1,137,179,231	\$22,297,632	\$1,858,136	\$14,865,088
ENTERAL NUTRITION	\$191,927,229	\$195,765,773	\$3,838,545	\$319,879	\$2,559,030
GLUCOSE MONITOR	\$330,015,023	\$336,615,323	\$6,600,300	\$550,025	\$4,400,200
HIGH FREQUENCY CHEST WALL OSCILLATION DEVICES	\$64,143,540	\$65,426,411	\$1,282,871	\$106,906	\$855,247
HOSPITAL BEDS/ACCESSORIES	\$68,652,378	\$70,025,426	\$1,373,048	\$114,421	\$915,365
INFUSION PUMPS & RELATED DRUGS	\$872,092,079	\$889,533,920	\$17,441,842	\$1,453,487	\$11,627,894
LOWER LIMB PROSTHESES	\$698,693,338	\$712,667,204	\$13,973,867	\$1,164,489	\$9,315,911
LUMBAR SACRAL ORTHOSES (LSO)	\$511,870,793	\$522,108,209	\$10,237,416	\$853,118	\$6,824,944
NEBULIZER AND RELATED DRUGS	\$761,390,925	\$776,618,743	\$15,227,818	\$1,268,985	\$10,151,879
NPWT	\$111,006,173	\$113,226,296	\$2,220,123	\$185,010	\$1,480,082
OSTOMY SUPPLIES	\$269,239,418	\$274,624,206	\$5,384,788	\$448,732	\$3,589,859
PARENTERAL NUTRITION	\$251,553,483	\$256,584,553	\$5,031,070	\$419,256	\$3,354,046
PMD	\$424,769,904	\$433,265,302	\$8,495,398	\$707,950	\$5,663,599
SURGICAL DRESSINGS	\$317,192,010	\$323,535,850	\$6,343,840	\$528,653	\$4,229,227
UROLOGICALS	\$408,957,517	\$417,136,667	\$8,179,150	\$681,596	\$5,452,767
WHEELCHAIR OPTIONS/ACCESSORIES	\$57,443,773	\$58,592,648	\$1,148,875	\$95,740	\$765,917
WHEELCHAIR SEATING	\$72,232,277	\$73,676,923	\$1,444,646	\$120,387	\$963,097
WHEELCHAIRS MANUAL	\$104,039,208	\$106,119,992	\$2,080,784	\$173,399	\$1,387,189





QUESTION #6

What documentation changes have taken place for suppliers?

DOCUMENTATION

- Face-to-Face encounters
- Signatures
- ABNs
- Prior Authorization
- Replacement



- CMS Interim Final Rule
- Face-to-Face Encounter Requirements
 - For the duration of the PHE, CMS is waiving the F2F and in-person requirements in the DME.
 LCDs and NCDs.
 - The waiver does not apply to the PMD F2F requirement since that's required by law/statute, but valid telehealth visits will suffice for these.



- Face-to-Face Requirements
- IFR
 - NCDs and LCDs contain clinical conditions a patient must meet to qualify for coverage of the item or service. Some NCDs and LCDs may also contain requirements for face-to-face, timely evaluations or re-evaluations for a patient to initially qualify for coverage or to qualify for continuing coverage of the item or service.
 - ...on an interim basis, we are finalizing that to the extent an NCD or LCD (including articles)
 would otherwise require a face-to-face or in-person encounter for evaluations, assessments,
 certifications or other implied face-to-face services, those requirements would not apply during
 the PHE for the COVID-19 pandemic.



- Signature Issues
 - CMS COVID-19 Provider Burden Relief FAQ
 - "Is CMS waiving signature requirements on proof of delivery slips in response to the COVID-19 pandemic, for Dates of Service within the PHE for the COVID-19 pandemic?"
 - Yes
 - "Suppliers should document in the medical [patient] record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19."
 - CMS DMEPOS Flexibilities Document
 - Signature and proof of delivery requirements waived
 - When signatures cannot be collected.
 - Suppliers should document in the patient record the date of delivery and that a signature could not be obtained because of COVID-19.



ABN Delivery

- Current notice delivery instructions provide flexibilities for delivering notices to beneficiaries in isolation.
 - Hard copies of notices may be dropped off by any hospital worker able to safely enter.
 - Contact phone number provided for beneficiary questions.
- When hard copy delivery not possible
 - Notices may be delivered via email if beneficiary has email access in isolation room.
 - Notices should be annotated with circumstances of delivery
 - Who completed delivery
 - When and to where was the email sent
- Notices may be delivered via telephone or secure email to beneficiary representatives offsite.



- ABN Delivery
 - Notices should be annotated with circumstances of delivery
 - Person delivering notice via telephone
 - Time of call, or
 - Where and when the email was sent
 - Review the specifics of notice delivery as set forth in Chapter 30 of the Medicare Claims Processing Manual https://www.coms.gov/media/137111 (PDF).
 - Note: CMS-R-131 (Exp. 3/2020) remains valid until further notice.
 - https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN



- Prior Authorization
 - DMEPOS: CMS Flexibilities to Fight COVID-19.
 - Prior Authorization in DMEPOS: CMS is pausing the national Medicare Prior Authorization program for certain DMEPOS items.
 - All prior authorization has been paused. The pause is voluntary—meaning that if suppliers want
 to continue submitting prior authorization requests to the DME MAC for PMDs and/or the
 support surfaces, they may.
 - If suppliers do not submit the prior authorization request, the claim will be paid; and the claim will be reviewed after the PHE.



- Prior Authorization
 - Claims submitted with a non-affirmation, or bypassing prior authorization, will require the following on initial and subsequent rentals
 - CR modifier to be appended
 - Narrative indicating "COVID-19"
 - Claims bypassing prior authorization may be selected for post-payment review after the PHE has ended
 - Addition of lower limb prosthetics to prior authorization delayed due to the PHE.



Replacement

- CMS released information on their ability to allow flexibilities and issue waivers (when authorized) to pay for replacement DMEPOS that a Medicare beneficiary owns or purchased.
- This is normal guidance they issue during natural disasters, but this is not a situation where
 equipment is likely to be lost or destroyed.
- Release indicated that Medicare-enrolled suppliers can contact their DME MAC for assistance and guidance.
- May be instances unique to this PHE where patients get stranded away from home due to a shelter in place or quarantine and they don't have access to their own equipment.



- Waiver under §1135 or §1812(f) of the Social Security Act.
- Medicare Fee-for-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19) SE20011.
 - Includes information on CR Modifier usage on claims under waiver.
 - Links to Q&As with a §1135 waiver or, when applicable, a §1812(f) waiver are posted and Q&As applicable without any §1135 or other formal waivers.
 - https://www.cms.gov/files/document/se20011.pdf





QUESTION #7

Are there other regulatory areas that have been affected by the PHE?

AUDITS & APPEALS

- CMS has suspended contractor audit activity.
- This includes pre-payment medical reviews conducted by DME MACs under the TPE and post-payment reviews conducted by SMRC and RAC.
- No additional documentation requests will be issued for the duration of the PHE.
- TPE, SMRC, and RAC reviews that are in process will be suspended and claims will be released and paid.



AUDITS & APPEALS

- CMS is allowing DME MACs, QIC, and Part CIRE
 - To allow extensions to file an appeal.
 - Waive requirements for timeliness for requests for additional information to adjudicate appeals.
 - To process an appeal even with incomplete Appointment of Representation forms.
 - To process requests for appeal that don't meet the required elements.
 - To utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.



- Toll-free hotlines to enroll and receive temporary Medicare billing privileges.
- National Supplier Clearinghouse Hotline Telephone Number: 1-866-238-9652.
- To initiate temporary billing privileges, you will be asked to provide limited information including, but not limited to
 - Legal Name
 - National Provider Identifier (NPI)
 - Social Security Number
 - A valid in-state or out-of-state license
 - Address information and contact information (telephone number)



- The NSC will attempt to screen and enroll the supplier over the phone and will notify the physician or non-physician practitioner of their approval or rejection of temporary Medicare billing privileges during the phone conversation.
- The NSC will follow up with a letter via email to communicate the approval or rejection of the temporary billing privileges.
- Suppliers will be assigned an effective date as early as March 1, 2020. They may bill for services furnished on or after the effective date and until the PHE declaration is lifted.



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- Billing privileges are being granted on a provisional basis as a result of the PHE declaration and are temporary.
- Upon the lifting of the PHE declaration, you will be asked to submit a complete CMS-855S enrollment application in order to establish full Medicare billing privileges, following the NSC's review of your application.
- Failure to respond to the MAC's request within 30 days of the notification will result in the deactivation of your temporary billing privileges.



- All clean web applications will be processed within 7 business days and all clean paper applications in 14 business days.
- Waive the following screening requirements for all enrollment applications received on or after March 1, 2020
 - Application Fee
 - Criminal background checks associated with fingerprint-based criminal background checks (FCBC)
 - Site-visits
- State licensure requirements still apply unless waived by the state.



- All revalidation activities are suspended during PHE.
- CMS is not requiring accreditation for newly enrolling DMEPOS suppliers and extending any expiring supplier accreditation for a 90-day time period.
 - CMS will monitor all billing activity during the emergency and continue to reassess this requirement.
 - Aberrant billing practices may be subject to further action.
 - [AAHomecare has gone on record, with the accreditation organizations, opposing this.]



OUTSTANDING ISSUES

- Ongoing communications with CMS/clarifications and additional guidance
 - Oxygen CMN (Initial and Recert) with suspension of NCDs/LCDs
 - Claims processing issues
 - Grandfathering of beneficiaries
 - PMD Telehealth clarifications where objective clinical measurements required
 - Documentation requirements in the PIM
 - Standard Written Order
 - Current orders that have expired in PHE
 - Requested extension of 9 months.
 - Other NCD and LCD considerations
 - Access to medical records and documentation still an issue.



OUTSTANDING ISSUES

- Ongoing communications with CMS/clarifications and additional guidance
 - Payer Changes to Medicare FFS
 - Assessment of Equipment
 - TPE suspended
 - Close out current audits and pay
 - Future TPE audits
 - Setups during PHE concerns
 - 5-Year RUL
 - Oxygen and exchange of equipment





QUESTION #8

What are the federal government, states, and PBM's doing to lessen the burden on pharmacies during the pandemic?

FEDERAL GOVERNMENT STEPS

- Medicare is granting broader discretion to pharmacies.
- Part D sponsors are relaxing plan requirements.
- FDA is relaxing standards to allow greater access to drugs.



PHARMACY BENEFIT MANAGER (PBM) STEPS

- Pharmacy Benefit Manager (PBM) Temporary Policy Changes in Response to COVID-19
 - Many PBMs have implemented policy changes in light of the COVID-19 outbreak. Some of the changes are detailed for the various payers.1

• 1. Payer information on slides may be out of date, so please verify on your own.



CVS CAREMARK

(because of regular changes, information may be imperfect—must be verified)

- CVS Pharmacy home delivery of medications charges have been waived.
- Members are encouraged to refill maintenance medications with a 90-day supply or up to plan maximum.
- CVS is offering 90-day maintenance medication prescriptions for insured and Medicare members.
- CVS Caremark is waiving early refill limits on 30-day prescription maintenance medications for all members.
- Pharmacies are to follow dispensing guidelines regarding the use of medications for COVID-19 that have been established in certain states. In states with no guidelines, pharmacies are limited in the dispensing of COVID-19 treatment to a 10-day supply with no refills.



EXPRESS SCRIPTS (ESI)

- Members which present early refills of medications will be permitted to have those prescriptions filled. However, such refills will be closely monitored and may be audited.
- Pharmacies are not required to obtain signatures from patients during the COVID-19 pandemic, unless otherwise required by law. Documentation in place of patient signatures may include, but is not limited to, the following:
 - Pharmacist notes in a logbook of the prescription number and date of service;
 - The cash register receipt that includes prescription numbers;
 - Text message or email from the patient;
 - Note on the hard copy; or
 - Electronic annotation in system



EXPRESS SCRIPTS (ESI)

- ESI is suspending all network pharmacy field and desk audits. However, ESI noted that its suspension of audits does not apply to fraud, waste, and abuse investigations or other exceptions that may be required by law.
- Express Scripts Home Delivery will allow for 90-day supply of medications to be shipped to members with free shipping.



- Hydroxychloroquine limited to 30 tablets within a 90-day time period with an automatic bypass (contingent therapy lookback edit) for members who have utilized at least a 60day supply within the past 120 days.
- Chloroquine will be limited to 30 tablets (or 40 tablets for 250 mg strength) within a 90day time period.
- If members require doses of hydroxychloroquine or chloroquine that exceed the quantity limit, their prescribers may complete a prior authorization following the standard process.
- Members are permitted to refill prescriptions early and refill-too-soon edits are being waived.



 Prior Authorizations (PAs) for member medications set to expire on or before May 1, 2020 will be extended for an additional 90 days past May 1, 2020. However, drugs with significant abuse potential (opioids) or those that are generally dosed for finite durations or intermittently (i.e., hepatitis agents, fertility agents) as identified by OptumRx will follow the normal process for renewals.



Existing members calling to refill specialty medications, will be offered a one-time, 90-day supply of key specialty medications instead of the traditional 30-day supply. This does not apply to patients newly initiating specialty therapy or certain other drugs including acute medications, controlled substances, drugs with limited expiration dating, drugs in short supply, drugs whose monthly ingredient cost exceeds \$10,000, drugs subject to REMS programming requiring 30-day dispensing and monitoring, drugs where storage/handling issues would increase risk of waste, drugs dosed less frequently than once monthly, and office-administered injectable/infusible therapies.



- Retail pharmacies are not subject to mailing restrictions in accordance with CMS guidance.
- Signature requirement of mailed medications temporarily waived. Delivery logs of impacted claims are to be documented with verbiage, "Impacted by COVID-19".
- Signature requirements for medications picked up at the pharmacy are also waived, and signature logs of impacted claims are to be documented with verbiage, "Impacted by COVID-19" and initialed by pharmacy staff.
- OptumRx Home Delivery does not charge members shipping fees (with the exception of expedited shipping costs).



HUMANA

- Humana has implemented a process to allow providers to override "refill-too-soon" edits for members refilling prescriptions early. However, such refills will be closely monitored and may be audited.
- Signature requirements for mail or home delivery for retail-only pharmacies are waived for a limited time to allow members to choose to receive medications from a retail-only pharmacy via mail or home delivery. This waiver will be for claims with dates of services in March and April 2020. (Humana is evaluating whether to extend this date and will communicate that decision in a pharmacy bulletin.) If pharmacy is unable to obtain a member signature, Humana will accept point-of-sale documentation showing the date and time that the prescription was sent out for delivery for claims with dates of service in March and April 2020.



HUMANA

- Brand drugs are permitted in place of generic drug shortages without reimbursement penalty to the pharmacy.
- No new desktop and onsite audits and all in progress desktop and onsite audits are suspended until April 30, 2020. This does not apply to audits requested by CMS or initiated due to fraud, waste, and abuse concerns.





KEY TIP FOR PHARMACIES WITH PAYER RELATIONSHIPS

Stay Tuned Daily to Changes by PBMs





KEY TIP FOR PHARMACIES WITH PAYER RELATIONSHIPS

Stay Tuned Daily to Changes by PBMs1



QUESTION #9

What are key COVID-19 employment laws affecting health care providers?



- Families First Coronavirus Response Act passed in March 15, 2020
- Effective April 1, 2020
- Umbrella for various smaller acts, including
 - Emergency Paid Sick Leave Act (EPSLA); and
 - Emergency Family and Medical Leave Expansion Act (EFMLEA)
- Applied to private employers with fewer than 500 employees



CARES ACT

- Coronavirus Aid, Relief, and Economic Security Act passed in March 25, 2020
- Umbrella for various smaller acts, including
 - Keeping Workers Paid and Employed Act (including the Paycheck Protection Program); and
 - Assistance for American Workers, Families, and Businesses.
- Most provisions are intended to assist small businesses with fewer than 500 employees.



OSHA STANDARDS: AN OLDIE BUT A GOODIE

- Occupational Safety and Health Act of 1970 (OSH Act)
- While some states have enacted OSHA-approved state plans, Texas like many other states defaults to general federal OSHA rules.
- The OSH Act's general duty clause, or safe workplace standard, requires employers to furnish a place of employment free from recognized hazards that are causing or likely to cause death or serious physical harm to employees.
- Under the OSH Act, employers have a duty to ensure that a COVID-19 positive employee stays away from the workplace and does not infect coworkers.



GENERAL NEGLIGENCE STANDARD

- Employers have a duty to furnish a workplace free from most COVID-19 hazards.
- Failing to mitigate the risks of COVID-19 may be a breach of this duty.
- Issues arise when an employer knew or should have known that an employee was exposed to COVID-19 in the workplace and failed to take precautions to mitigate this exposure.
- The lawyers will be swarming after the crisis has ended.



REASONS FOR PAID SICK LEAVE

- The employee is subject to a federal, state, or local quarantine or isolation order related to COVID-19, and the employer still has work for the employee.
- The employee has been advised by a health care provider to self quarantine because of COVID-19 concerns.
- 3. The employee is experiencing symptoms of COVID-19 and seeking a medical diagnosis.
- 4. The employee is caring for an individual: (a) subject to an order of quarantine or isolation; or (b) who has been advised by a health care provider to self quarantine.
- 5. The employee is caring for his or her minor child whose school or place of care has been closed or whose childcare provider is unavailable due to COVID-19 precautions.
- The employee is experiencing any other substantially similar condition later specified by the Secretary of Health and Human Services.



QUARANTINE OR ISOLATION ORDER

- A quarantine or isolation order includes
 - Quarantine, isolation, containment, shelter-in-place, or stay-at-home orders issued by any federal, state, or local government authority.
 - When a federal, state, or local government authority has advised categories of citizens (e.g., of certain age ranges or of certain medical conditions) to shelter in place, stay at home, isolate, or quarantine, causing those categories of employees to be unable to work even though their employers have work for them.



PAID LEAVE ISSUE

May we require employees to utilize paid leave first? NO.

- Employers may not require employees to use other available paid leave before using paid sick leave under the EPSLA.
- At an employee's election, he or she may choose to utilize paid leave instead of leave under the EPSLA. Employees may choose to use their paid leave first if their reason for leave under the EPSLA only entitles them to two-thirds of their regular rate of pay.



DOCUMENTATION ISSUE

Question:

What documentation may employers require from employees?

Answer:

It depends on what kind of leave then employee is requesting.



REQUIRED DOCUMENTATION

- An employee is required to provide his employer documentation containing the following information prior to taking paid leave under the EPSLA or EFMLEA:
 - 1. Employee's name;
 - 2. Date(s) for which leave is requested;
 - 3. Qualifying reason for leave; and
 - 4. Oral or written statement that the employee is unable to work because of the qualified reason for leave.
- Additional documentation requirements are required depending on the type of leave requested.



REQUIRED DOCUMENTATION

- Isolation order: name of the government entity that issued the quarantine or isolation order.
- Advice to self-quarantine: name of the health care provider.
- Childcare:
 - 1. The name of the son or daughter being cared for;
 - 2. The name of the school, place of care, or childcare provider that has closed or become unavailable; and
 - 3. A representation that no other suitable person will be caring for the son or daughter during the period for which the employee takes the EPSLA or EFMLEA leave.



SMALL BUSINESS EXEMPTION

Question: Is my company excluded because we have less than 50 employees?

Answer: Not the whole business.

Small businesses, with fewer than 50 employees, might be exempt from providing leave to care for a minor child due to school or place of care closures or childcare provider unavailability due to COVID-19 related reasons when doing so would "jeopardize the vitality of the small business as a going concern."



SMALL BUSINESS EXEMPTION

A small business may claim this exemption for individual employees if an authorized officer of the business has determined that:

- 1. The provision of paid sick leave or expanded family and medical leave would result in the small business's expenses and financial obligations exceeding available business revenues and cause the small business to cease operating at minimal capacity;
- 2. The absence of the employee or employees requesting paid sick leave or expanded family and medical leave would entail a substantial risk to the financial health or operational capabilities of the small business because of their specialized skills, knowledge of the business, or responsibilities; or
- 3. There are not sufficient workers who are able, willing, and qualified, and who will be available at the time and place needed, to perform the labor or services provided by the employee or employees requesting paid sick leave or expanded family and medical leave, and these labor or services are needed for the small business to operate at a minimal capacity.



HEALTH CARE PROVIDER EXCLUSION

Question: Is my company excluded because it qualifies as a "health care provider"?

Answer: No, but individual employees may be excluded.

An employer whose employee is a health care provider or an emergency responder may exclude such employee from the EPSLA and/or EFMLEA.



HEALTH CARE PROVIDER EXCLUSION

- Doctor's office
- Hospital
- Health care center
- Clinic
- Post-secondary educational institution offering health care instruction
- Medical school
- Local health department or agency
- Nursing facility

- Retirement facility
- Nursing home
- Home health care provider
- Pharmacy
- Any facility that performs laboratory or medical testing, pharmacy, or any similar institution, employer, or entity
- Entity that contracts with any of these institutions to provide services or maintain operation of the facility



HEALTH CARE PROVIDER EXCLUSION

- Employers should determine which of their workers are "health care providers" on a case-by-case basis.
- The DOL also encourages employers to be judicious when using the definition of "health care provider" to exempt employees from the provisions of the FFCRA.



EMPLOYEE LEAVE

Be Smart with Employee Sick Leave and Extended FMLA Leave

- Consider options including employee's accrued PTO, vacation, sick leave, etc.
- Consider option of unpaid leave of absence, even if employer is not an FMLA employer.
- Carefully consider situations where extended FMLA leave applies under new law.
- Consider furlough.
- Consider effect of possible employment decisions (particularly terminations) on your application (if any) for Paycheck Protection Program!





QUESTION #10

What are the top 5 tips for employers during this pandemic?



Create a Protocol Designed to Guide Your Team and Mitigate Your Risk of Liability

- Incorporate most recent CDC guidance plus any other guidance from state boards, payers, etc.
- Include guidance to protect employees from customers/patients/clients and from one another.
- Date it and issue to all employees ensure (properly distanced) employee training imperfect usually better than none.
- Think of the scared employee, and prepare accordingly.





Call a time-out and buy yourself a day if necessary





General employment policies still apply, and employers may address employee misbehavior, BUT...remember this a pandemic.





Document employer decision making.

SHOW YOUR WORK





Think long term before making crucial, short-term decisions involving employees.



RESOURCES

- CMS Current Emergencies: https://www.cms.gov/About-CMS/Agency-
 Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
- Coronavirus Waivers & Flexibilities: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers
- Telehealth Toolkit for General Practitioners: https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf
- End-Stage Renal Disease Providers Toolkit: <u>https://www.cms.gov/files/document/esrd-provider-telehealth-telemedicine-toolkit.pdf</u>



RESOURCES

- CMS FAQ: https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf
- Impact on Appeals: https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf
- White House COVID Taskforce updates: https://www.coronavirus.gov/



RESOURCES

- Includes DME MAC specific information including: Accelerated/Advance Payment, and answer to questions, and additional resources
- Jurisdiction A: https://med.noridianmedicare.com/web/jddme/topics/emergencies-disasters
- Jurisdiction B: https://www.cgsmedicare.com/jb/covid-19.html
- Jurisdiction C: https://www.cgsmedicare.com/jc/covid-19.html
- Jurisdiction D: https://med.noridianmedicare.com/web/jddme/topics/emergencies-disasters



DISCLAIMER

The information provided in this webinar was accurate as of April 17, 2020. Please know that the federal, state, and local governments are issuing updated information on a regular basis.

This presentation is not intended to be legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only. You should consult your attorney for legal advice.





THANK YOU

QUESTIONS?



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