



NHIA TALK INFUSION WEBINAR

Legislative Efforts and the Implications of CMS' Recently Announced Interim Final Rule for Home Infusion Providers

April 2, 2020

Agenda

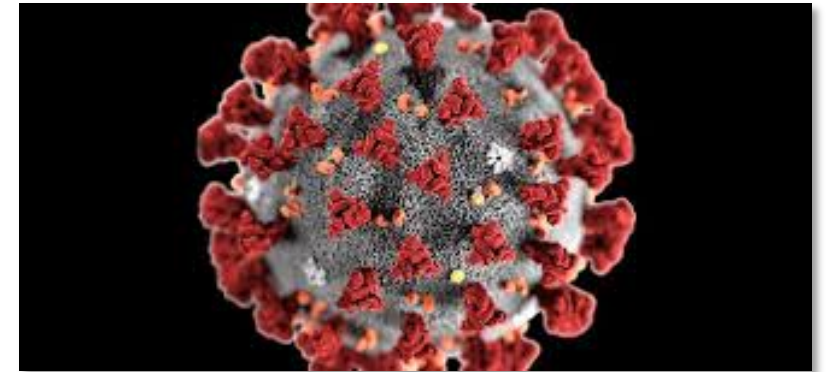
- NHIA Updates
 - Actions in response to COVID-19
 - 2020 Education Programs / Conference Contingency plan
 - 2021 Annual Conference information
 - Industry Trends Report Update
- Legislative Activities
- Analysis of the CMS Interim Final Guidance in Response to COVID-19
- Q&A



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NHIA Resources for COVID-19

- Industry guidance for sterile compounding, operations
 - Protecting employees
 - Maintaining quality sterile compounds
 - Managing surge demand
 - Nursing conservation strategies
- Commercial payer recommendations
- Letters and calls to HHS
- Advocacy to expand HIT services
- COVID Resource Center – NHIA website, open access



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Operations Guidance for COVID-19

General

- Conduct COVID-19 screening
- Consider extended hours/shifts
- Prepare plan for workforce disruptions to meet current demand
- Implement PPE conservation immediately

Nursing

- Prioritize PPE for direct patient contact
- Use N95 respirators for positive or presumed positive COVID-19 patients
- Screen all patients
- Limit time in home
- Use disposable supplies when possible (i.e. BP cuffs, thermometers)
- Implement nursing visit conservation strategies

Pharmacy

- Prioritize drug supply and create alternative recommendations
- Complete screening during refill coordination
- Reduce lab draws where clinically appropriate

Infusion Suites

- Avoid use if suite cannot be separated from infusion pharmacy operations
- Chairs min. 6 feet apart
- Schedule at 50% capacity
- Complete screenings remotely and before patient enters suite or in a segregated, cleanable area



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Sterile Compounding Guidance During COVID-19 Outbreak

- As of 4/1/2020, 47% of compounders have implemented conservation
- HD Compounding: must use PPE
- Consider increased surface sampling of PEC
- Develop risk-based approach to assign BUDs
- Garbing strategies to conserve PPE

Masks

- Do not re-use disposable masks
- Use clean, low-linting material to cover nose & mouth

Gowns:

- Reuse disposable gowns if intact and not soiled;
- Washable, dedicated, long-sleeve garments (i.e. lab coats-laundry daily)
- Consider using non-sterile sleeves when re-using gowns

Shoe:

- Do not reuse disposable shoe covers
- Cleanable dedicated shoes

Head and hair covers

- Use shower caps or reusable fabric head and hair cover (1 per shift)

Gloves:

- Use sterile gloves beyond expiratory date
- If no sterile gloves, then use non-sterile + frequent IPA



NHIA COVID-19 Resource Page



http://www.nhia.org/COVID_19_Resource_Center.cfm



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2020 Conference Credit Options

- NHIA will be hosting a Summer Education Series with virtual content that was planned for the 2020 Annual Conference.
- This free education series will provide the latest on home and specialty infusion including best practices and information you need for your organization.
- We ask that you consider converting your existing 2020 registration costs to support the National Home Infusion Foundation's (NHIF) work or our PITCH In campaign.



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JOIN NHIA IN AUSTIN

For the 2021 Annual Conference

FEBRUARY 27 – MARCH 3, 2021



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Industry Trends Report

- Available April 2020
- Content
 - Provider Services
 - Patient Characteristics
 - Revenue & Payer Analysis
 - Referral trends
 - Operational Metrics
 - Top therapies/drugs/diagnoses



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Litigation Update

- Judge Leon has withdrawn from the case, and our case is has been reassigned to Judge Tim Kelly, a recent appointee.
- Our case should appear on his docket as an “old case” meaning he’ll need to decide the case no later than September 30.
- Will urge the judge to offer a quick decision given the time sensitivity of the matter.



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Legislative Update

- Congress passed 'Phase III' of their COVID-19 response legislation on March 27.
- NHIA's ask:
 - Remove the face-to-face requirement for reimbursement.
 - Expand Medicare home infusion benefit to cover all home infusion drugs, including those covered under Part D.
- 'Phase III' expanded access to telehealth and ended Medicare sequestration, but included no specific home infusion provisions.
- Congress is expected to take up 'Phase IV' in late April.



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Advocacy Efforts

- Part B Permanent Fix: Introduction of S. 3457/H.R. 621
 - Require payment to be made every day a medication is infused, regardless of whether a skilled professional is present in the patient's home.
 - Enumerate the specific services to be included in the reimbursement, including the extensive pharmacy services that are performed remotely.
 - Takes effect in 2021.
- Part D expansion for COVID-19 Response
 - Option 1: Amend above and expand through waiver authority
 - Option 2: Collaborative effort with BIO on single bill
 - Option 3: Pass both NHIA and BIO bills



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Joint Stakeholder Proposal

- Provide services payments for drugs billed to B or D, no change to how drugs are billed
- No physical presence requirement
- Would clearly reimburse pharmacy and/or nursing services
- Allow pharmacy and home health to overlap
- Definition of home infusion provide includes physician, PA, NP, pharmacy



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CMS Rule in Response to COVID-19

Section E. Direct Supervision by Interactive Telecommunications Technology

- Relaxes the requirement for physicians to provide supervision in the same location as the service
- May substitute the use of real-time, audio and video technology to supervise services incident-to a physician order
- Physicians may sub-contract a practitioner (which includes a home infusion therapy services supplier) to provide the in-person service
- The services may be either face-to-face, or non-face-to-face can be billed as long as the physician is providing supervision through AV tech “when needed”
- These services are not billable if the patient is under a HH episode of care.
- Homebound requirements could be waived for infusion patients if the physician certifies they are medically contraindicated from leaving the home.



COVID-19 Interim Rule – DME

Clinical Indications for Certain Respiratory, Home Anticoagulation Management and Infusion Pump Policies During the PHE for the COVID-19 pandemic,

it is possible that patients receiving services for respiratory related indications will be required to receive care in unexpected settings, including the home. This may be necessary as COVID-19 and other patients are shifted across healthcare settings to accommodate an increase in patient volume.

Therefore, we are finalizing on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump

- NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic. These policies include, but are not limited to:
 - NCD 240.2 Home Oxygen.
 - NCD 240.4 Continuous Positive Airway Pressure for Obstructive Sleep Apnea.
 - LCD L33800 Respiratory Assist Devices (ventilators for home use).
 - NCD 240.5 Intrapulmonary Percussive Ventilator.
 - LCD L33797 Oxygen and Oxygen Equipment (for home use).
 - NCD 190.11 Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management.
 - NCD 280.14 Infusion Pumps.
 - LCD L33794 External Infusion Pumps.

At the conclusion of the PHE for the COVID-19 pandemic, we will return to enforcement of these clinical indications for coverage.



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COVID-19 Reimbursement Policy Modifications

- CMS is addressing each silo individually (Part A and B)
 - Relaxing administrative burden, enrollment process, paperwork and reporting, audits, etc.
 - Expanding use of telehealth
 - Expanding homebound for Home Health
- Providing guidance to Part C and Part D
 - Refills, increase dispense days, relax PAs, patient signature log/POD
- BUT, NOT FILLING THE PART D COVERAGE GAP for items and services
- DME Policies (CARES Act)
 - Suspends Sequestration May 1- December 31, 2020
 - Modifies non-CBA area rates: 50/50 Rural, 75/25 non-rural



CARES Act

- Suspends the 2% sequestration May 1- December 31, 2020
- Modifies non-competitive bid area (CBA) rates:
 - Rural 50/50 blend
 - Non-rural 75/25 blend
- SBA loans – forgive portion of the loan for 2 months payroll, benefits, mortgage/lease, utilities. See TRP summary



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DME Waivers

- **Signature Requirements:** CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.
- **Accelerated/Advance Payments:** In order to increase cash flow to providers impacted by COVID-19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing.



Burden Relief

- CMS will suspend audits: DME MAC, TPE, RAC, SMRC
- Expedite enrollment: processed in 7 days, 14 days for paper
 - Waive
 - Application fee
 - Criminal background checks associated with fingerprint-based criminal background checks
 - Site-visits
 - Postpone all revalidation actions
- Waive signature requirement for POD



NHIA Recommendations to Insurers

- Health and Human Services and Commercial Payers
- Reduce administrative burden
- Expand networks
- Fill coverage gaps
- Allow for additional days supply (Enteral)



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