NHIA TALK INFUSION WEBINAR

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

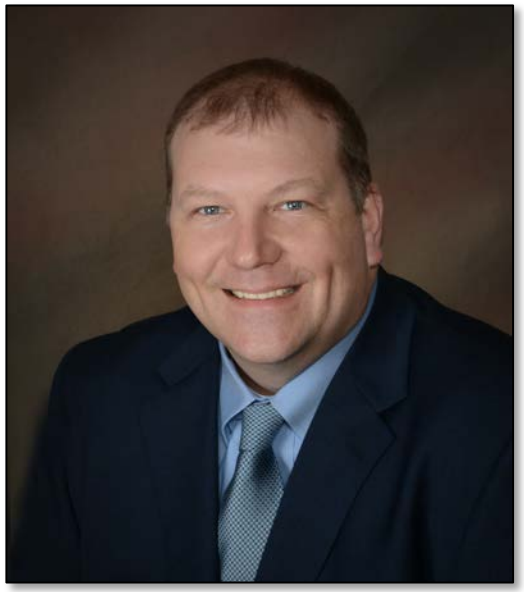
April 29, 2020

NHIA
National Home Infusion Association

Today's Presenters

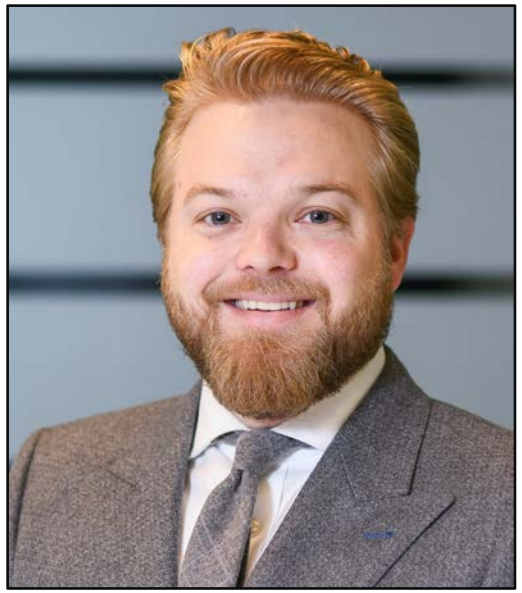
Connie Sullivan

President and CEO



Bill Noyes

Senior Vice President of Reimbursement Policy



Shea McCarthy

Director Legislative Affairs, NHIA
Senior VP, Thorn Run Partners

Agenda

- NHIA COVID resources
- COVID-19 compounding guidance
- Legislative landscape
- Cares Act and CMS Policy Update
- Q&A

Resources 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
- Physician tools
- Patient infographic

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

PPE Survey

- N=29 to date (insufficient sample for extrapolation)
- 58% experiencing mask shortages
- 35% re-using disposable gowns
- 55% report shortage of N95s
- 55% report difficulty obtaining hand sanitizer
- 44% have treated a C-19 patient at home
- 10% have treated a C-19 patient in the suite

Compounding Guidance - USP

United States Pharmacopeia (USP) Published Documents:

- USP Response to Shortages of Garb and PPE for Sterile Compounding During COVID-19 Pandemic (3/18/20)
- Operational Considerations for Sterile Compounding During COVID-19 Pandemic (4/11/20)
- Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic (3/25/20)

Compounding Guidance - FDA

Food and Drug Administration Published Documents:

- Temporary Policy Regarding Non-standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency
- Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

PPE Recommendations

	USP	FDA
Masks	Reuse not recommended; Don a clean, low-lint fabric face mask prior to entering compounding area.	Reuse during same shift, store within compounding area to minimize contamination. May extend use to subsequent days if no visible discoloration, damage. Disinfect when use multiple times with appropriate agent*
Gowns	Reuse disposable gowns. Store in classified area. Clean, washable fabric gowns acceptable.	Not addressed
Head/Hair Cover	Don a clean, fabric cover per shift is acceptable alternative.	Not addressed
Shoe Covers	Reuse of disposable covers not recommended. Use dedicated shoes.	Reuse of disposable covers not recommended. Use dedicated shoes.
Gloves	Not addressed	Use beyond shelf-life, or non-sterile gloves disinfected frequently using appropriate agent for compatibility with glove material

Check with your state Board of Pharmacy regarding local regulations.

BUD Recommendations

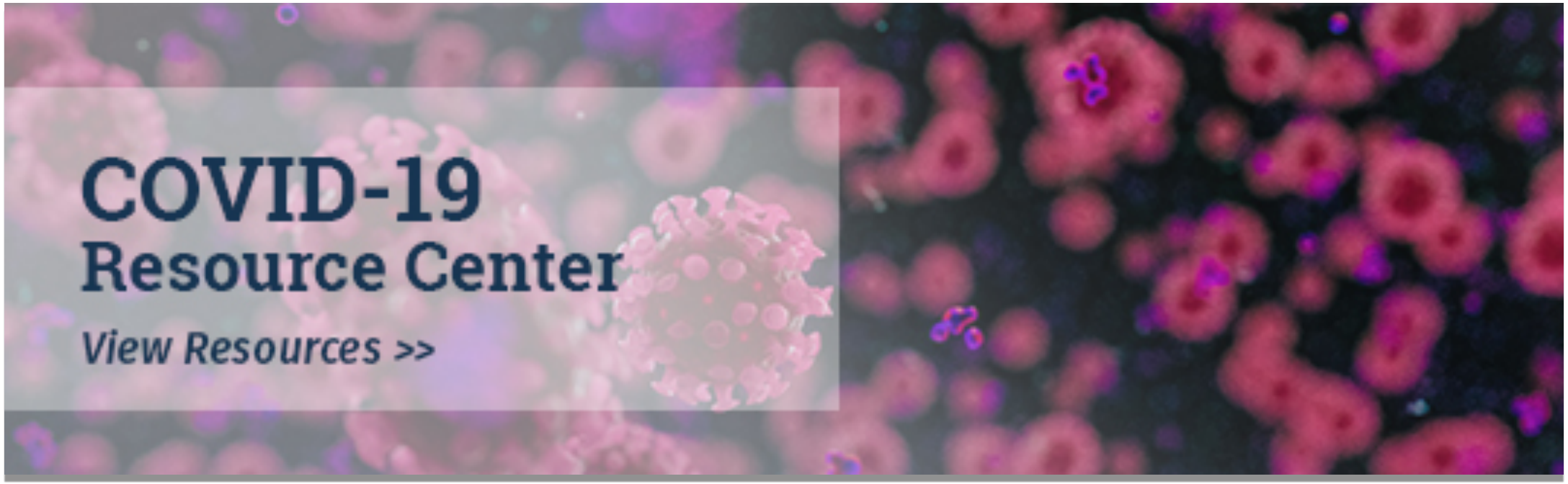
	USP	FDA
	If garb and procedures do not deviate from current Chapter <797> (2008), then BUDs may be assigned as follows:	If nonstandard garb then all CSPs use BUDs below, terminal sterilization, or alternate risk mitigation strategies that provide comparable protection.
Low/Med CSPs prepared in SCA	RT: 12 hrs REF: 24 hrs	Not addressed
Low Risk CSPs prepared in suite	RT: 4 days REF: 14 days FZ: 45 days	RT: 24 hrs REF: 3 days FZ : 45 days Recommends sterilizing filter during compounding
Med Risk CSPs prepared in suite	RT: 4 days REF: 10 days FZ: 45 days	

Check with your state Board of Pharmacy regarding local regulations.

Cleaning, Certifications, Env. Monitoring

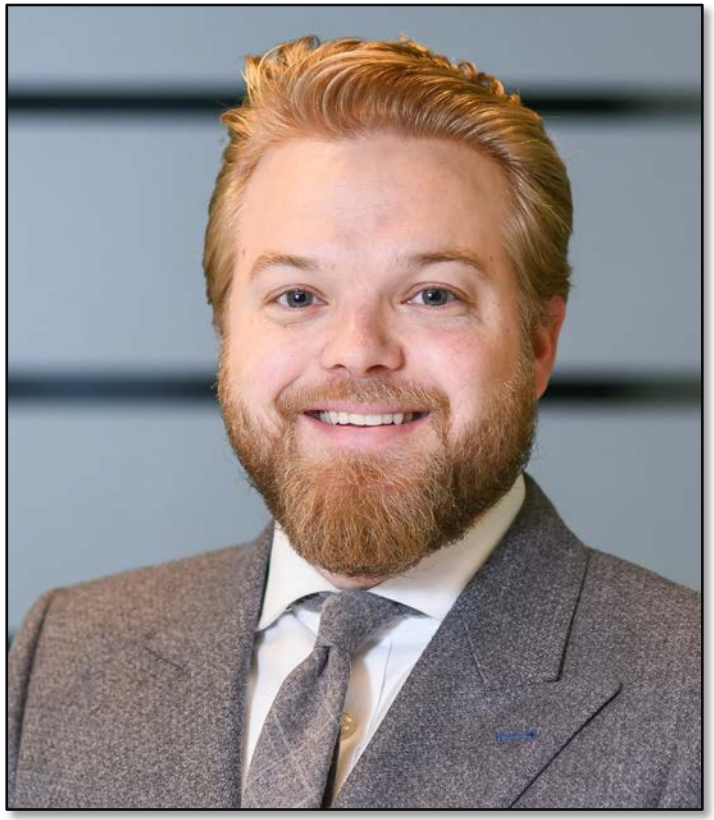
	USP	FDA
Cleaning	Follow facility established policies and procedures: -Routinely clean & disinfect high touch surfaces -Use EPA-registered disinfectants For SARS-CoV-2	Increase cleaning frequency, increase use of sporicidal agents
Certifications	Primary & Secondary controls should not be used without initial certification. Interval between certifications should not exceed 12 months.	Not addressed
EM	Consider increased environmental monitoring: Increased surface sampling of PECs	Increase environmental sampling: -fingertip after each shift -surface sampling in PEC -”passive” air-sampling

NHIA COVID-19 Resource Page



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

Shea McCarthy
Director of Legislative Affairs, NHIA
Senior VP, Thorn Run Partners



NHIA TALK INFUSION WEBINAR

Congressional Response to COVID-19

- Congress passed ‘Phase 3’ of their COVID-19 response, the CARES Act, on March 27.
  - Provided $100B in emergency funding to providers, expanded access to telehealth, and ended Medicare sequestration.
  - No specific home infusion provisions.
- ‘Phase 3.5’ passed on April 23, replenishing the PPP (+$310B) the provider funding stream (+$75B).
- Congress is expected to take up ‘Phase 4,’ the CARES Act 2, in May.
  - Top priorities: infrastructure, state & local, business liability, health care.

Home Infusion Concept Legislation

- NHIA and over 160 stakeholders are supporting “concept legislation” that would expand access to home infusion during the pandemic.
- Key provisions:
  - Provides 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 nursing services
  - Offers flexibility in provider types

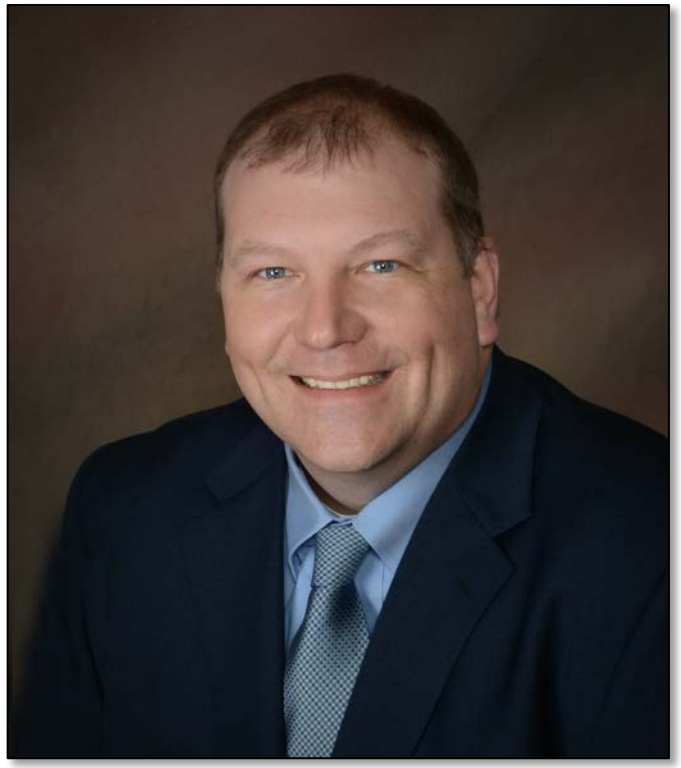
Notable Supporters

NHIA TALK INFUSION WEBINAR

CMS' Interim Final Rule

- Requires that the physician arrange for the delivery of drug, equipment, and supplies to the patient's home, while subcontracting for the nursing-related services to a home health agency or home infusion therapy provider.
  - NHIA Comments: "While currently, prescribing physicians direct home infusion care, their role is not typically to oversee each infusion… This is unnecessary in home infusion and precludes pharmacists and nurses from working at the top of their licenses to coordinate and direct the administration of home infusion therapies — as they have for decades in the commercial market."
  - Notably, there has been no demonstrated interest from providers in leveraging this sort of contracting arrangement.
- NHIA's proposal to CMS:
  - Waive the physician presence requirement for reimbursement;
  - Expand professional services payments to Part D covered drugs.
- A second Interim Final Rule is currently under review at OMB.

Bill Noyes
Senior Vice President of
Reimbursement Policy



COVID-19 Home Infusion Policies

- Telehealth
- Part B DME Program
- Home Health
- Provider Relief Funds (Grants)
- Sequestration
- Rate Relief in Non-CBAs
- 2021 Permanent HIT Services Benefiy
- Xembify

Telehealth for Home Infusion Therapy

- Allows for billing for physician incident to billing for drugs administered in the home.
- Physician to bill as if provided in office/clinic
- Physician to provide support via Audio Visual
- Physician can subcontract with Home Health or Home Infusion Therapy Supplier for in home services.
- Wholly separate from Home Health

Home Health – Home Bound Requirement

CMS considers beneficiaries to be “confined to the home” (that is, “homebound”) if it is medically contraindicated for the patient to leave the home. For example, a beneficiary could be considered “homebound” if: (1) a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

Part B DME Infused Drugs

- Non-enforcement of clinician indications for External Infusion Pump (EIP) Policy
- Per the IFR FAQs this is limited to the drugs in the EIP policy.

See the following list of Frequently Asked Questions (FAQs) for more information on the home infusion therapy benefit, including a list of covered infusion drugs: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf

Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J2278	Injection, ziconotide, 1 microgram
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg

Category 2	
J1555 JB[1]	Injection, immune globulin (cuvitru), 100 mg
J1559 JB	Injection, immune globulin (hizentra), 100 mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9200	Injection, floxuridine, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

Provider Relief Funds -$100B Allocated for Providers

- First disbursement of $30B began 4/10/2020 “HHSPAYMENT”
- @ 6.2% of 2019 Part B Claims
- Attestation – Within 30-days of receiving funds
- Terms and Conditions – What can I use these funds for?

Provider Relief Funds – Round 2

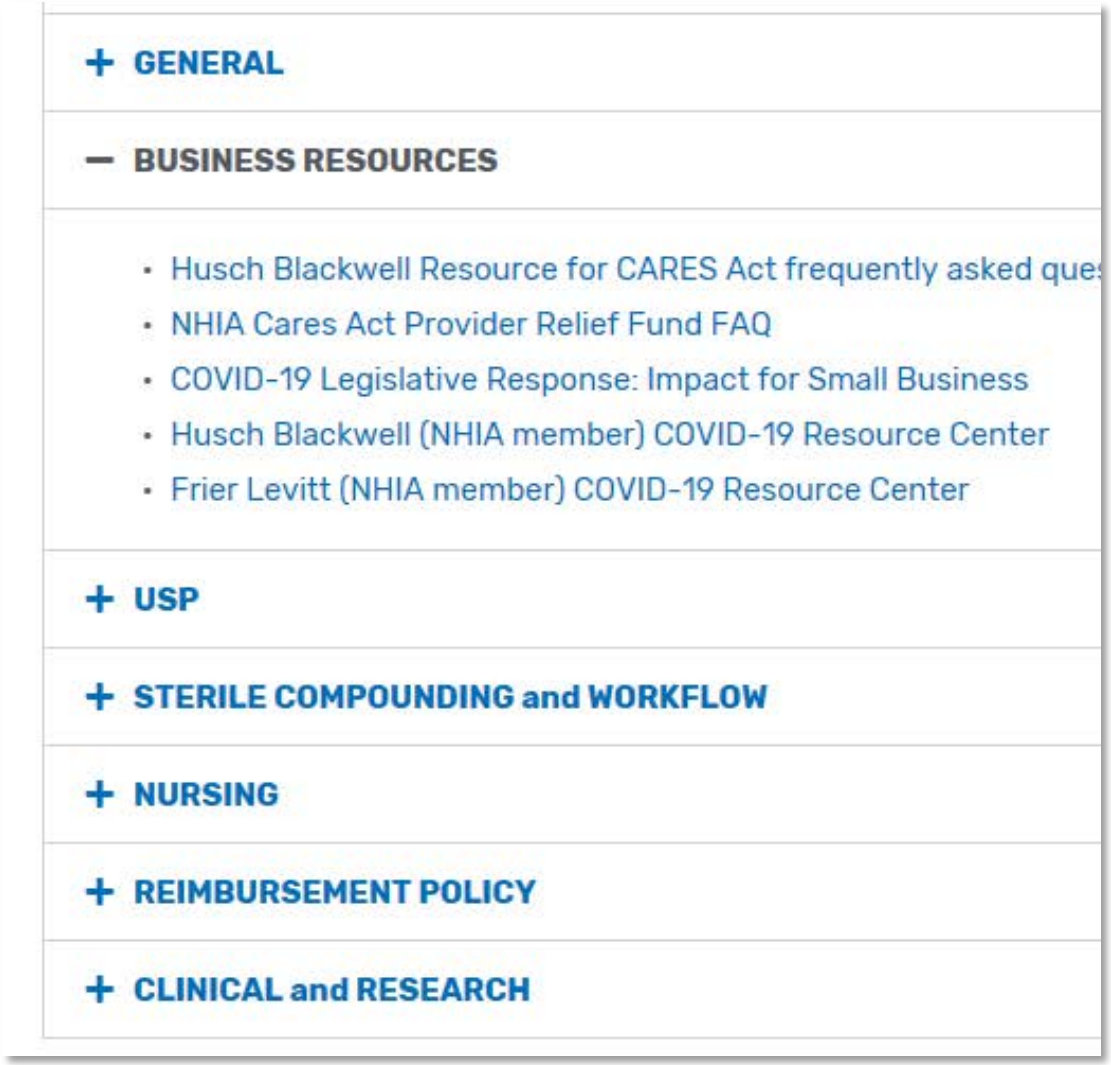
The second round of funding includes an additional $20 billion for providers nationwide, $10 billion for hospitals in highly impacted areas, $10 billion for rural providers, and $400 million for the Indian Health Service. It also establishes a program to fund COVID-19 care for the uninsured.

HHS has published a list of frequently asked questions pertaining to the $50 billion general allocation of the COVID-19 provider relief fund. In addition, providers receiving funds must agree to a set of terms and conditions, including reporting and documentation requirements, charging only in-network rates for COVID-19 care, and certifying that the funds will only be used to prevent, prepare for, and respond to the outbreak. Those that do not agree must contact HHS within 30 days to remit the payment.

https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html

NHIA COVID-19 Resource Center

- https://www.nhia.org/covid_19_resource_center/



CARES Act

- Sequestration suspended May 1, 2020- Dec. 31, 2020
- Rate relief in non-competitive bidding areas
  - 50/50 blended rate in Rural
  - 75/25 blended rate in non-rural non-CBAs

Medicare Permanent HIT Services Timeline

February 1, 2020

Accrediting Organization (AO) Application Deadline

November 2020

Home Health Final Rule

Stakeholder education begins

A/B MAC will begin accepting applications.

January 30, 2021

A/B MAC 855B Provider Application deadline. Effective date (billing rights) 30 days prior to application filing. 45-70 days to process application.

Home Health Proposed Rule

June 2020

Implementation Date – Medicare HIT (Nursing) Services Benefit Begins

January 1, 2021

HIT Services Accrediting Organizations (AO)

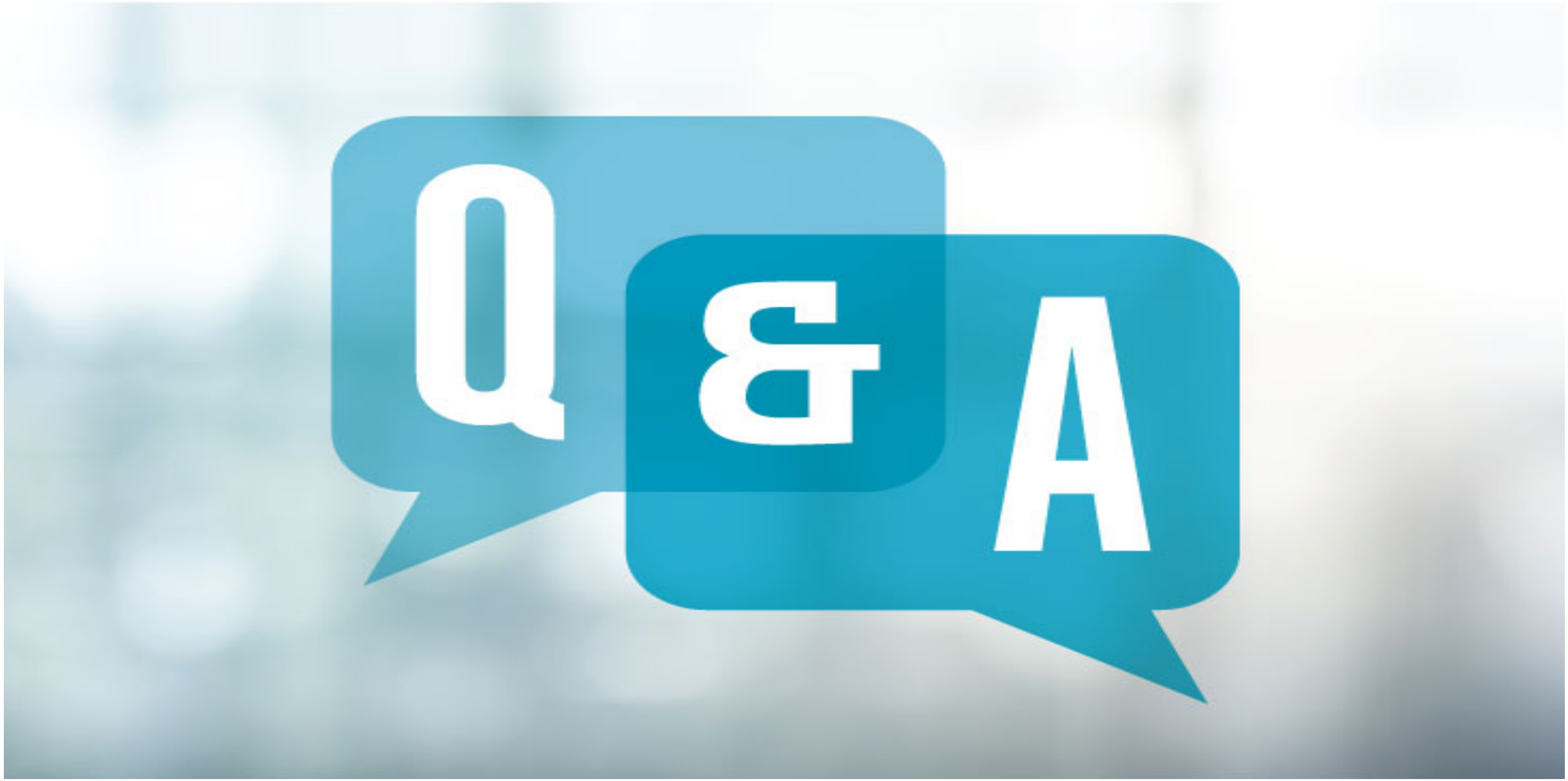
- [x] The Joint Commission - Approved
- [x] URAC - Approved
- [x] ACHC - Approved
- [ ] The Compliance Team
- [ ] CHAP
- [ ] NABP

Xembify

- Covered under the EIP LCD for PIDD effective 5/31/2020
  - FDA approved on July 3, 2019
  - First DME infused drug to go through the new LCD Reconsideration Process

NHIA Advocacy to CMS

- Letter to HHS
  - ✓ Proof of Delivery (POD)
  - ✓ Suspend audits
    - Delay WOPD and face-to-face requirements
    - Waive qualifying criteria (clinical indications) for PN and Enteral
    - Allow G-code service billing of remote services
    - Delay Implementation of Round 2021 of Competitive Bidding
    - Grandfather HIT accreditation for 2021



NHIA TALK INFUSION WEBINAR