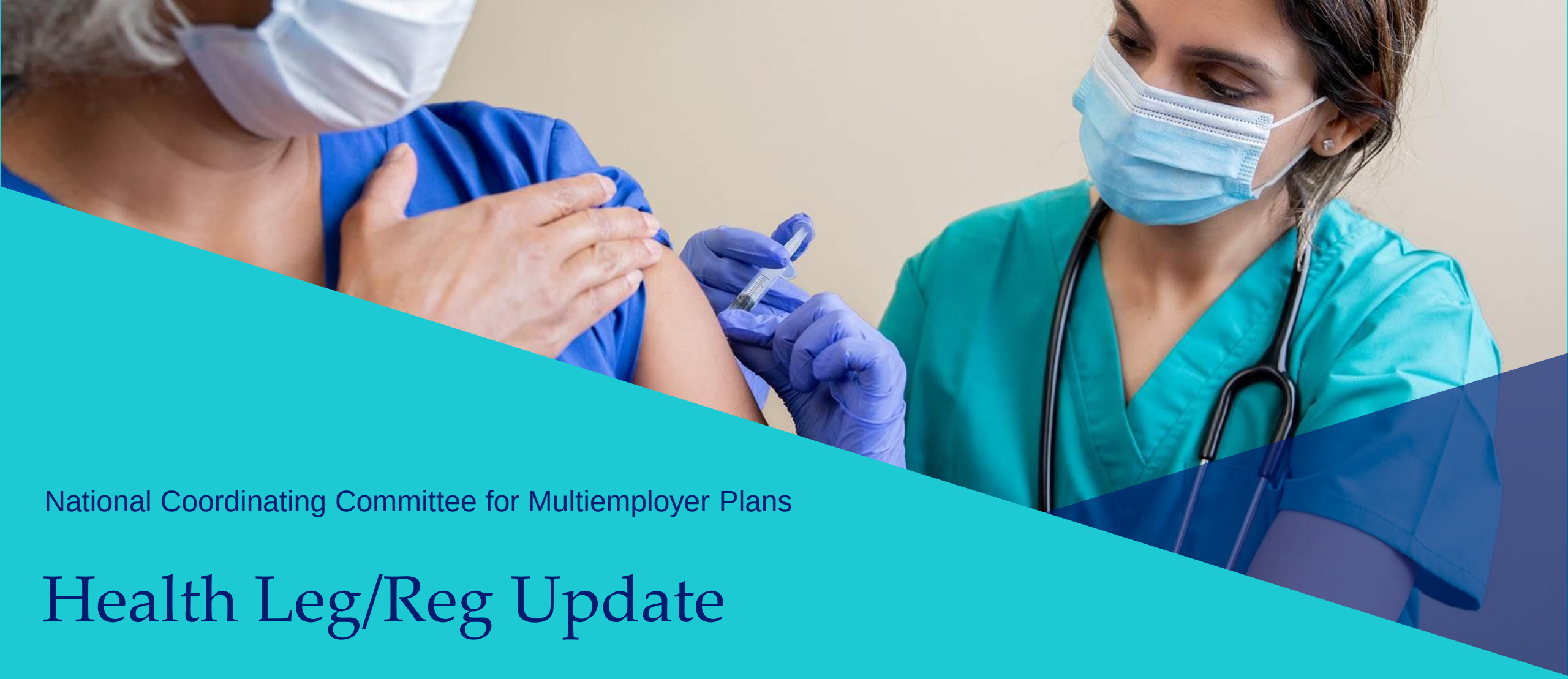


National Coordinating Committee for Multiemployer Plans

Health Leg/Reg Update

2022 Lawyers and Administrators Meeting
Washington DC

March 22, 2022 / Kathryn Bakich

Segal

Agenda

COVID-19 Tests and Vaccines

No Surprises Act

Transparency Rule

New Reporting Requirements

COVID-19 Tests and Vaccines

Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines

Items and Services relating to COVID-19 testing or diagnosis: In-Vitro diagnostic tests that are 1. Approved, cleared, or authorized by the FDA; 2. Developer has requested or intends to request Emergency Use Authorization (EUA); 3. Developed in and authorized by certain States; or 4. Other tests determined by HHS.	Payable without cost-sharing, prior authorization, or medical management requirements Includes serological tests that are used to detect antibodies against the virus	March 18, 2020 through the Public Emergency Period (FFCRA) *Most recent extension of PHE was January 14, 2022 for an additional 90 days*
Items or services furnished during a provider "visit" that results in an order for, or administration of, a COVID-10 diagnostic test.	Payable without cost-sharing, prior authorization, or medical management requirements	March 18, 2020 through the Public Emergency Period (FFCRA)
Payments to contracted/non-contracted providers	Pay the negotiated rate or cash price listed on the provider's public website	March 27, 2020 through the Public Emergency Period (CARES Act)
COVID-19 tests intended for at-home testing, when ordered by an attending health care provider who has determined that the test is medical appropriate	Payable without cost-sharing, prior authorization, or medical management requirements	June 2020 through January 14, 2022 (FAQ 43)

Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines (2)

Over-the-Counter (OTC) COVID-19 tests, including tests obtained without the involvement of a health care provider; Test must be approved or authorized to be self-administered and self-read without the involvement of a health care provider	Payable without cost-sharing, prior authorization, or medical management requirements; Safe harbor permits limit to 8 tests per month per person Plans may not limit test reimbursement to only participating providers. Safe harbor permits plans that have a direct coverage relationship through a participating pharmacy network and a direct-to-consumer shipping program to limit reimbursement for tests obtained from non-participating retailers to no less than the actual price or $12 per test, whichever is lower.	January 15, 2022 through Public Emergency Period (FAQ 51, 52)
Testing, (including OTC tests) for employment purposes	Not payable	FAQ 44, FAQ 51
Section 213(d) medical expenses include OTC COVID-19 tests, masks, hand sanitizers, wipes, and PPE	Payable from FSA, HRA, HAS; However, an individual cannot be reimbursed more than once for the same expense	IRS Guidance, FAQ 52

Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines (3)

	Vaccines and Treatment	
COVID-19-related preventive services recommended by the USPSTF or the ACIP must be covered by non-grandfathered group health plans within 15 business days after any such recommendation is made. Later guidance clarified that plans are required to cover any COVID-19 vaccine authorized under an EUA or BLA immediately upon being approved	Non-GF plans must pay at negotiated rate or reasonable amount (Medicare rates are reasonable)	ACA requires coverage of vaccines in-network; CARES Act requires coverage OON through the Public Emergency Period
Treatment for COVID-19	There is no federal requirement to cover treatment	NA

COVID-19 OTC Tests: What we're seeing . . .

- PBMs were not ready to comply with FAQ 51 when it was released, and FAQ 52 provided needed flexibility
- As of March, PBMs were still modifying their COVID-19 OTC test solutions
- Plan sponsors have been making good faith efforts to meet the safe harbor requirements but in the end are relying on service providers to provide appropriate solutions

No Surprises Act and Transparency Rule

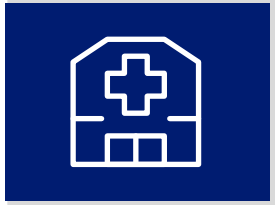
No Surprises Act Litigation

- In its decision in *Texas Medical Association v. U.S. Department of Health and Human Services,* a Texas District Court held that the Departments erred in presuming that the QPA would be the determinative amount selected by an arbitrator during the IDR process unless credible information demonstrates that the QPA is materially different from the appropriate out-of-network rate
- EBSA issued a Memorandum indicating the Departments will:
  - Withdraw guidance related to the parts of the Interim Final Rule the court invalidated;
  - Offer training on the revised guidance for certified IDR entities and disputing parties
  - Open the IDR process for submissions through the IDR Portal. If the 30-day open negotiation period required by the Act has expired, the Departments will permit the parties to request IDR within 15 business days following the opening of the IDR Portal

No Surprises Act Implementation Challenges

- No Surprises Act
  - Participants must be protected: No balance billing, limits on cost-sharing
  - Developing the QPA may be challenging
    - Calculation of QPA when there are multiple networks or direct contracts not addressed in rules
  - Set up IDR process and reporting from service providers
    - Monitor number of NSA claims, open negotiation requests, IDR requests and IDR results
    - Pay attention to out-of-network agreements, which may need to be modified for payments to service providers, amount of negotiation authority
  - Provider contracting

Steps Preceding the Federal IDR Process



Start

An item or service results in an NSA covered charge for emergency services from an OON provider or facility, a charge for non-emergency services from an OON provider at an in-network facility, or air ambulance service from an OON air ambulance company

Initial Payment or Notice of Denial of Payment

Must be sent by the plan no later than 30 calendar days after a clean claim is received

Initiation of Open Negotiation Period

An open negotiation period must be initiated within 30 business days beginning on the day the OON provider receives either the initial payment or denial

Open Negotiation Period

The parties must exhaust a 30 business-day open negotiation period before either party may initiate the Federal IDR process

Federal IDR Process Overview

Federal IDR Initiation

Either party can initiate the Federal IDR Process by submitting a Notice of IDR initiation to the other party and the Departments within 4 business days after the close of the open negotiation period.

Must include preferred certified IDR Entity

Selection of Certified IDR Entity

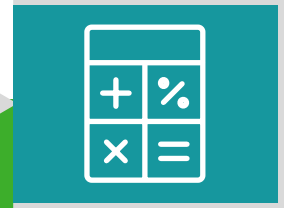
Accept the IDR Entity selected by initiator, or object and propose another Entity.

If no agreement, Departments will select within 6 business days. IDR Entity must certify it has no conflict

Submission of Offers and Fee Payment

Parties must submit their offers not later than 10 business days after selection of the certified IDR Entity.

Parties must pay fees directly to IDR entities, who will hold fees in trust, as well as administrative fee



Selection of Offer

Certified IDR Entity has 30 business days after its date of selection to determine the payment amount and notify the parties and Departments of its decision.

IDR Entity must select one of the offers

Payments Between Parties, Fee Refunds

Must pay amount due within 30 calendar days of determination.

IDR Entity must refund prevailing party's IDR Entity fee within 30 business days

Transparency Implementation Challenges

- Transparency
  - July 1 machine readable files for medical (in-network, OON allowed)
  - 2023 and 2024 Price Comparison internet tool (need further regulatory guidance on relationship of Transparency Rule to NSA)
  - Prescription Drug Reporting December 27, 2022
  - Gag Clause Attestation sometime in 2022
  - Air Ambulance reporting

Transparency Guidance Still Needed

- Machine readable files – are Rx required?
- Price comparison tool – do transparency rules apply to NSA requirements?
- Prescription drug reporting – when will plan sponsors receive guidance? Will HIOS system be used?
- Gag clause – guidance on what constitutes gag clause needed; attestation portal being tested
- Air ambulance reporting awaiting final rule

NSA/Transparency References

- Texas Medical Assn v. HHS https://www.bloomberglaw.com/public/desktop/document/TexasMedicalAssociationetalvUnitedStatesDepartmentofHealthandHuma/3?1645714500
- EBSA Memorandum https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act/memorandum-regarding-continuing-surprise-billing-protections-for-consumers
- IDR Portal https://www.cms.gov/nosurprises
- FAQs about IDR https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-FAQs-Federal-Independent-Dispute-Reolution-Process.pdf
- IDR Process Guide *Appears to have been pulled from website*
- Prescription Drug Reporting Guide https://www.cms.gov/files/zip/cms-10788.zip

Thank You!

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