



NCCMP Annual Conference

# 2020 Regulatory Update

October 14, 2020 / Kathryn Bakich

# Agenda

**Regulatory Update**

**Prescription Drug Executive Orders and Regulations**

# Transparency/Disclosure Proposed Rule



- Final “transparency” regulation sent to White House for review
- Proposed rule published Nov. 27, 2019 would require non-grandfathered group health plans (and health insurers) to provide the following:
  - Real-time cost-sharing information to plan participants, upon request, via an internet self-service portal
    - Provider-specific information, searchable by billing code or description of the item/service)
  - Public disclosure via the internet of in-network negotiated rates and out-of-network allowed amounts for specific services
    - Files would have to be machine-readable and updated monthly
- NCCMP filed comments on January 29, 2020

# Worker Classification Proposed Rule



In September, DOL announced a proposed rule addressing how to determine whether a worker is an employee under the Fair Labor Standards Act (FLSA) or an independent contractor

Proposal would:

- Adopt an “economic reality” test to determine a worker’s status as an FLSA employee or an independent contractor;
- Identify two “core factors”: the nature and degree of the worker’s control over the work; and the worker’s opportunity for profit or loss based on initiative and/or investment;
- Identify three other factors that may serve as additional guideposts, including: the amount of skill required for the work; the degree of permanence of the working relationship between the worker and the potential employer; and whether the work is part of an integrated unit of production

# Revisions to Paid Leave Rules



- DOL issued a revised Temporary Rule effective September 16, 2020, implementing the paid sick leave and expanded family and medical leave provisions of the FFCRA
- Rule was revised after court decision overturned provisions
- Key issues:
  - Leave taken only if work would otherwise be available
  - Employer approval for intermittent leave
  - Revised definition of health care provider
  - Clarification regarding documentation
- DOL also issued new FAQs concerning paid leave and childcare

# Health Plan Audits

Both DOL and HHS continue active programs to audit group health plans.

- Multiemployer and large self-funded and fully-insured plans are targets of DOL audits.
- Nonfederal governmental plans are the focus of HHS audits.

## Focus includes:

- Grandfathered status
- Mental Health Parity and Addiction Equity Act (MHPAEA)
- Affordable Care Act (ACA) group market requirements
- HIPAA/ACA Wellness Program Rules

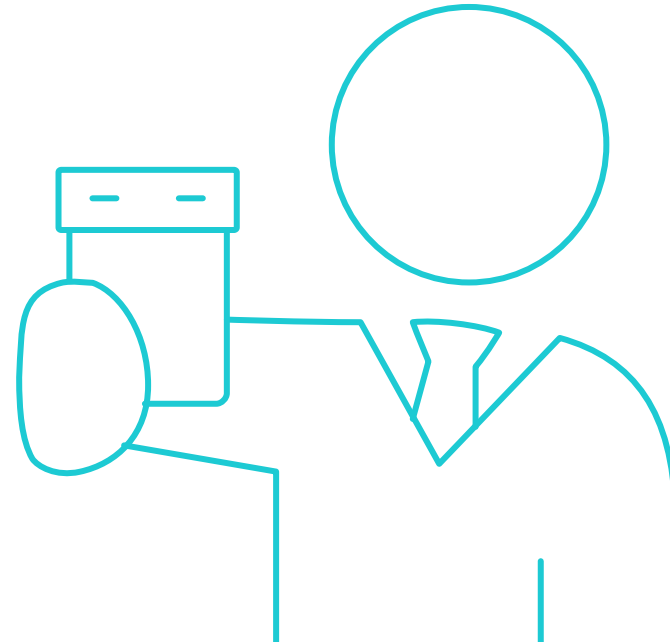


The background features a close-up photograph of two hands, one holding a white pill bottle and the other holding several white pills. The image is overlaid with a dark blue gradient and a diagonal split into a lighter cyan section at the bottom right.

# Executive Orders

# Prescription Drugs

- Administration issued *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* in May 2018
- A series of proposals and executive orders have followed
- No rules have been issued that apply to group health plans



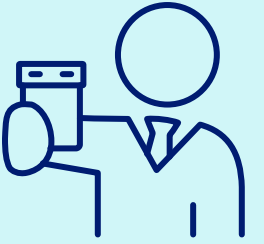


# Fall 2020 Executive Orders/Rules



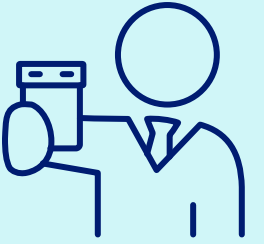
- Importation
- Elimination of PBM rebates and other non-point-of-sale price reductions in the Medicare Part D program
- Most Favored Nation Pricing
- Increased production of essential drugs in the US
- Mandated pass through of Federal discount on prices

# Final Rule on Rx Importation



- Permits States and other non-federal governmental entities to submit time-limited proposals to FDA for review and authorization; applications would have to demonstrate that the program would pose not additional risk to public safety and would result in significant reduction in cost of drugs
- Directs HHS to take action to expand safe access to lower cost imported prescription drugs by:
  - Permitting waivers allowing individual importation
  - Authorizing re-importation of insulin
  - Permitting importation of certain drugs from Canada

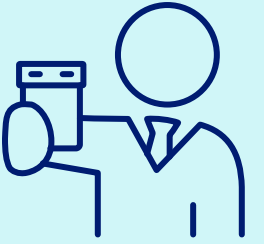
# Rebates and Non-Point-Of-Sale Discounts



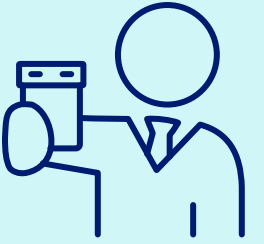
- An HHS rule proposed in February 2019 would have eliminated prescription drug rebates and permitted discounts to participants at the point-of-sale
- The Congressional Budget Office estimated in 2019 that the HHS proposed rule would cost the federal government \$177 billion over a 10-year period
- The Executive Order directs HHS to consider the rule but only if it can be done without increasing Federal spending, Medicare beneficiary premiums or patient out of pocket costs

# Executive Order on “Most-Favored-Nation”

- Medicare would pay no more than the lowest price for a pharmaceutical product sold in an OECD member country
- Medicare Part B rules were proposed for a demonstration project, but have not yet been finalized
- Administration extended the order to Medicare Part D, but no policies have been developed yet.



# Other Rx Executive Orders



- Mandated pass-through of federal discounts on prices:
  - Affects Federally Qualified Health Centers (FQHCs) that receive discounted prices through the 340B prescription drug program.
  - Order directs FQHCs to take action to ensure future grants available under the Public Health Service Act are conditioned upon the FQHC making insulin and injectable epinephrine available to individuals at discounted price.
- Production of prescription drugs in the U.S.:
  - Directs federal agencies to take actions to increase the production of essential medicines, medical equipment and protective gear in the U.S.
  - Order directs FDA to develop a list of essential drugs and supplies
  - Requires various agencies to address vulnerabilities in the drug supply chain

# Thank You!

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