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Special Bulletin

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Departments Release Proposed Rule on No Surprises Act Enforcement, Air Ambulance, and Agent/Broker Disclosure

The Departments of Health and Human Services (HHS), Labor, and Treasury and the Office of Personnel Management ("the departments") Sept. 10 released proposed rules implementing certain provisions of the No Surprises Act related to enforcement, air ambulance transparency, and agent and broker disclosures.

Key Takeaways

HHS proposes:

- What the role of states should be in overseeing and enforcing the provisions in the No Surprises Act.
- To establish a new process for investigating and enforcing provider requirements in the No Surprises Act.
- Updates to existing processes for investigating and enforcing plan/issuer violations of Public Health Service Act requirements, to include No Surprises Act requirements.

The proposed rules establish a process for investigating complaints of violations of the No Surprises Act patient protections and taking enforcement action, including imposing a civil monetary penalties (CMP) against both providers/facilities and plans/issuers. The departments also propose to increase transparency of air ambulance services through new disclosure requirements on plans/issuers and air ambulance providers. In addition, the rules include HHS-only proposals that would require insurers offering individual health insurance coverage or short-term, limited-duration insurance to disclose to enrollees and report to HHS any direct or indirect compensation provided by the insurer to an agent or broker associated with enrolling individuals in such coverage.

Comments on the proposed rules are due Oct. 18.

Highlights from the proposed rules related to enforcement of the No Surprises Act follow.

State vs. Federal Enforcement Authority. Under current policy, states have primary enforcement authority over plans and issuers with respect to all Public Health Service (PHS) Act requirements, which now incorporates many of the requirements under the No Surprises Act. However, in some instances, these responsibilities may transfer to the federal government, such as when a state notifies the Centers for Medicare & Medicaid

Services (CMS) that it has not enacted legislation or otherwise taken steps to enforce the PHS Act requirements, or the federal government determines that the state is failing to enforce the requirements. In such instances, CMS becomes the enforcement authority.

In this rule, HHS proposes a conforming amendment to specify that states also have primary enforcement authority over providers and facilities that practice in their states, as well as over providers and facilities that are out-of-state but provide telehealth services to individuals in their states. HHS also proposes updates to existing oversight regulations to align with the expanded scope, such as broadening the sources for information that would trigger a federal investigation of state enforcement to include state agencies that oversee providers and facilities (e.g., state departments of health). Overall, the processes for determining when a state is failing to substantially enforce PHS Act requirements and for transitioning from federal enforcement to state enforcement remain consistent with current regulations governing plans and issuers, but they are expanded to include the oversight of providers and facilities as well.

Federal Enforcement of Providers. HHS proposes a set of regulations implementing the process for investigating and enforcing provider and facility compliance with the No Surprises Act when CMS has assumed enforcement authority. The investigation process proposed aligns closely with the processes that already exist with respect to plans and issuers and that the departments propose to update through this regulation.

Similar to the process established for plans/issuers, HHS proposes that CMS may conduct an investigation of a provider/facility based on any information that indicates potential noncompliance with PHS Act requirements, such as consumer or other complaints, reports from state insurance departments or the National Association of Insurance Commissioners (NAIC), or reports from other federal or state agencies. Any entity or individual, or entity or personal representative acting on an individual's behalf, would be able to file a complaint. HHS also proposes to allow CMS to conduct random or targeted investigations, once again in alignment with the proposed changes to the insurer investigation process.

Upon identifying a potential violation, CMS would provide written notice to the provider or facility describing the information that prompted the investigation, if applicable. The notice also would state that a CMP may be assessed and that CMS may require a corrective action plan. The notice would provide a deadline for the provider or facility to respond; HHS anticipates a typical deadline of 14 days. Providers or facilities that receive a noncompliance notice could request an extension, and the departments note that possible rationales for extensions could include limited staffing resources or requests for clarification on the alleged violation. In response to a noncompliance notice, providers or facilities could submit any relevant documentation, including medical bills, notice and consent forms signed by the patient or patient representative, or proof of public disclosure of patient protections against balance billing. Providers or facilities also could submit any evidence documenting internal policies and procedures related to compliance. HHS proposes to limit enforcement action to six years from the date of alleged violations.

If a violation is confirmed, HHS proposes that CMS may impose a CMP of up to $10,000/violation, consistent with the No Surprises Act. In determining the CMP amount, CMS would consider the nature of the violation, the culpability of the provider or facility, the provider or facility's past history of violations, the frequency of violations (i.e., whether the issue represents a pattern or is an isolated incident), and the level of financial or other impacts on affected individuals. In instances where there are significant mitigating circumstances (e.g. no previous complaints against the provider or facility, demonstration that the issue is an isolated occurrence), the CMP would be assessed to be sufficiently below the $10,000 maximum. On the other hand, in instances where CMS determines there are aggravating circumstances (e.g. the violation indicates a widespread pattern of abuse, the provider or facility does not provide documentation showing that the violations were corrected) the CMPs would be close or equal to the $10,000 maximum. Finally, CMS may waive the CMP entirely if the provider or facility unknowingly violated the requirement, as long as any erroneous bills are withdrawn and patients are reimbursed within 30 days of the violation. HHS also proposes to codify the hardship exemption described in the No Surprises Act.

HHS proposes that, should CMS decide to impose CMPs, the agency would need to serve notice of the action in accordance with current practices, and the notice would need to specify the amount of the CMP, the information considered to determine the amount, and the process for appealing. HHS also proposes an appeals process in the proposed rules. If a provider or facility does not initiate the process within 30 days of the notice or show good cause for failing to initiate the process, the CMP determination would be final.

Federal Enforcement of Plans and Issuers. A process for CMS to investigate and enforce PHS Act violations by plans and issuers already exists. In this rule, HHS proposes slight modifications to these regulations; however, the overall process remains the same. The proposed rule details the basis for CMS initiating an investigation, including specifying that reports from providers and facilities can be the basis for an investigation (current regulations only cite reports from state insurance departments, the NAIC, and other federal and state agencies). HHS also proposes to modify the regulations to offer several different methods for entities or individuals to submit complaints, based on the individual's insurance and the nature of the complaint.[1] This would replace previous regulations directing complaints to the CMS regional offices, as the regional offices no longer process complaints. HHS proposes to allow CMS to conduct random or targeted investigations and market conduct examinations, including through the audits of plans' and issuers' compliance with the rules related to calculating the qualifying payment amount. Finally, HHS proposes several modifications and conforming amendments to the current regulations to clarify the current CMS enforcement procedures, including the process for notifying entities of a potential violation, the process for recipients of CMS warning notices to request an extension for

[1] The proposed rules cite the following sources for issuing a compliant: For PHS Act complaints regarding non-Federal governmental plans, consumers can email PHIG@cms.hhs.gov. For complaints with respect to issuers, consumers in states that are directly enforcing the applicable PHS Act provision are referred to the state department of insurance; for states in which CMS is directly enforcing PHS Act requirements, consumers can email MarketConduct@cms.hhs.gov. The list of current states in which CMS is directly enforcing one or more PHS Act provisions is available on the CMS website at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/compliance.

responding to the notice, the process for market conduct examinations, the process for determining the amount of the CMP and the appeals process. Based on current regulations, the maximum penalty on plans/issuers is $100/day per violation, adjusted annually. The 2020 adjusted amount was $162/day.

NEXT STEPS

Comments on the proposed rules are due Oct. 18.

FURTHER QUESTIONS

If you have further questions, please contact Ariel Levin, AHA's senior associate director of policy, at alevin@aha.org.