Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcements Summary of Proposed Rule

On September 16, 2021, the Departments of Treasury, Labor, and Health and Human Services (HHS) and the Office of Personnel Management (OPM) published in the Federal Register proposed **Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcements** (86 *Federal Register* (FR) 51730). The proposed rules amend and add to existing regulations to implement provisions of the No Surprises Act. The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021 (CAA),[1] established protections for enrollees of health plans from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers of air ambulance services under certain circumstances. It also established reporting requirements related to air ambulance services for plans, issuers, and air ambulance service providers and established other transparency requirements.

In the proposed rules, the Departments and OPM codify certain reporting and transparency requirements of the No Surprises Act including reporting about air ambulance services, and transparency requirements related to short-term, limited-duration (STLD) insurance, and to coverage offered in the individual health insurance market. In addition, HHS proposes a number of amendments to ensure that the existing processes used to investigate complaints and potential violations and to enforce the statute apply to the requirements of the No Surprises Act.

The Departments intend to issue regulations regarding the Federal independent dispute resolution (IDR) process, transparency requirements, and the patient-provider dispute resolution process later this year. **Comments are due October 18, 2021.**

I. Background

Under the Patient Protection and Affordable Care Act (ACA), enacted in 2010, non-grandfathered group or individual health plan issuers that cover emergency services in an emergency department of a hospital are required to make those services available without prior authorization and without regard to whether the provider of emergency services is an in-network provider. Under that requirement, plans and issuers may not impose any limitation on benefits for out-of-network emergency services that is more restrictive than the requirements that apply to in-network emergency services. The ACA did not, however, prohibit or limit the practice of

[1] P.L. 116-260

balance billing. As a result, providers of those services who do not participate in a plan's or insurer's network may bill patients for amounts in excess of amounts permitted as payment by the enrollee's plan or issuer – amounts that are often considerably more than the amount the plan or issuer has set as the enrollee's required cost sharing for the services.

The No Surprises Act expands on the ACA protections to establish protections against surprise out of network billing for emergency services including certain post-stabilization services, and for certain non-emergency services furnished by nonparticipating providers at certain participating health care facilities. Under certain conditions and with the enrollee's notice and consent, the limitations on balance billing and cost-sharing may be waived with respect to non-emergency and post stabilization services. A July 13th Interim Final Rule with Comment (86 *FR* 36872) implements the first set of those protections.

The regulations proposed below would codify the following provisions of the No Surprises Act:

- Providers of air ambulance services, health plans and issuers are required to report certain information regarding claims for air ambulance services and providers of those services to the Secretaries of HHS and Transportation. Under section 106 of the No Surprises Act the requirements are imposed for a period of 2 years after which the Secretary of HHS is required to issue a report summarizing the data. Civil money penalties are made available for providers of air ambulance services that do not comply with data submission requirements.
- The No Surprises Act requires a health insurance issuer offering individual health insurance coverage or STLD insurance to disclose to enrollees in such coverage and to report annually to HHS the direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. Those requirements become effective December 27, 2021.

In addition, to the extent that states do not enforce the requirements of the No Surprises Act applicable to providers, facilities, and air ambulance providers, HHS enforcement regulations would be modified to permit HHS to undertake enforcement processes parallel to those applicable to health insurance issuers and to apply civil money penalties where appropriate. While states are the primary enforcers of requirements applicable to health insurance issuers and to providers and facilities (including air ambulance providers), in states that fail to enforce a Public Health Service (PHS) Act provision, that enforcement duty defaults to HHS.

The Departments note that with respect to certain provisions of the No Surprises Act that are effective as of December of 2021 or January of 2022 (certain transparency requirements, continuity of care, provider network directories, prohibitions on gag clauses, for example) regulations may not be issued before their effective dates. The Departments intend to provide for prospective applicability dates for forthcoming regulations to ensure there is a reasonable time for plans, issuers, providers, or facilities to comply with the new or clarified requirements.

The Departments consulted with stakeholders on the proposed rules. They held listening sessions with consumers, health care providers, facilities, providers of air ambulance services, employers, agents, brokers, health plans and health insurance issuers, advocacy groups, and the

actuarial community. They also solicited input from state representatives and consulted with the National Association of Insurance Commissioners, state regulators, issuers, trade groups, consumer advocates, employers, and other interested parties.

II. Proposed Rules Related to Air Ambulance Services Reporting

The Departments describe proposed reporting requirements for providers of air ambulance services and for plans and issuers offering group or individual health insurance coverage. The Departments explain that air ambulance services have frequently resulted in surprise medical bills and summarize the background and research substantiating the problem and describing the costs for such services.

As GAO, other federal agencies, and advocacy groups examined the issue, they found there to be a lack of comprehensive data on air ambulance costs, transports, and arrangements between providers and insurers. GAO, as well as an Advisory Committee formed by the Secretary of Transportation, recommended collection of data to improve understanding of the industry and increase transparency.[2] In response to those recommendation, the No Surprises Act requires health plans and health insurance issuers as well as air ambulance provider to make reports to HHS regarding those services for a period of two years. In addition, the statute requires HHS, in consultation with the Secretary of Transportation, to issue a comprehensive public report summarizing the data and providing an assessment of the state and certain aspects and characteristics of the air ambulance market.

The Departments codify the No Surprises Act reporting requirements applicable to providers of air ambulance services and plans and issuers in HHS amendments to 45 CFR 149. In addition, the Departments of Treasury and Labor, and the OPM with respect to all other types of health plans as well as issuers of federal employee health plans, propose amendments to indicate that health plans, health insurance issuers, and Federal Employee Health Benefits carriers will meet the No Surprises Act requirements if they submit reports to HHS consistent with the requirements specified in 45 CFR 149.

Definitions. Two new definitions would be added to 45 CFR 149.30:

- An "air ambulance base" would be defined as a site from which a provider of air ambulance services operates to provide air ambulance services.
- A "National Provider Identifier (NPI)" would be defined by reference to the definition in 45 CFR 162.406.

Health Plan and Health Insurance Issuer Reporting

Reporting requirements applicable to plans and issuers would be incorporated into 45 CFR 149.230. In general, HHS would require a group health plan and insurance issuer offering group or individual health insurance coverage to submit a report to the HHS for each of calendar years 2022 and 2023. The 2022 report would be due by March 31, 2023 and the 2023 report would be due by March 30, 2023.

[2] Air Ambulance and Patient Billing Advisory Committee's Subcommittee on Prevention of Balance Billing, "A Report on the Prevention of Balance Billing", January 2021, DOT-OST-2018-0206-0026

A health insurance issuer that acquires a line or block of business would be responsible for submitting the report for the acquired plan for the full calendar year. The reporting requirement would also apply to issuers sold or acquired, combined or spun off. The Secretary may provide additional guidance for the purpose of this reporting at a later date.

For each claim for air ambulance services during the reporting period, plans and issuers must report the following data elements:

(1) Identifying information for the group health plan, plan sponsor, or issuer, and any entity reporting on behalf of the plan or issuer;
(2) Market type for the plan or coverage (individual, large group, small group, self-insured plans offered by small employers, self-insured plans offered by large employers, and Federal Employee Health Benefit (FEHB) program);
(3) Date of service;
(4) Billing National Provider Identifier (NPI) information;
(5) Current Procedural Terminology (CPT) code or Healthcare Common Procedure Coding System (HCPCS) code information;
(6) Transport information (e.g., aircraft type, loaded miles, pick-up zip code and drop-off zip code, whether the transport was emergent or non-emergent);
(7) Whether the provider has a contract with the plan or issuer to furnish air ambulance services;
(8) Claim adjudication information (e.g. claim paid, denied, or appealed, denial reason, appeal outcome); and
(9) Claim payment information (e.g. submitted charges, amounts paid, cost sharing).

Special rules would permit group health plans to satisfy the reporting requirements if the issuer offering the coverage reports the information on behalf of the plan pursuant to a written agreement. If the issuer fails to make the report, the issuer would be considered to be out of compliance and not the group health plan. A group health plan or issuer of group or individual coverage would be permitted to satisfy the reporting requirements by entering into a written agreement with another party (a health care claims clearinghouse or third-party administrator, for example) that reports the information. Under this arrangement, however, if the contractor fails to deliver the report, the plan or issuer could be considered to be in violation of the reporting requirements.

Air Ambulance Provider Reporting

Reporting requirements applicable to air ambulance providers would be incorporated into 45 CFR 149.460. As with insurers and health plans, air ambulance providers would be required to submit a report to HHS for each of calendar years 2022 and 2023. The 2022 report would be due by March 31, 2023 and the 2023 report would be due by March 30, 2023.

Parallel requirements for businesses that were acquired, combined, transferred, or sold would be established for air ambulance providers.

Air Ambulance Providers would be required to report the following data elements:

(1) Corporate information including identifying information for the company or organization, the parent organization, owner, proprietor, or sponsor of the provider of air ambulance services; information on air ambulance bases owned, leased, operated, or used; NPIs registered to the provider of air ambulance services;
(2) Air ambulance base information (e.g., Location; NPIs associated with the base; number, type, and other characteristics of the aircraft on the base; number and type of staff; number and type of air ambulance responses and transports per aircraft, etc.);
(3) Cost information for each air base (e.g., labor, facility, vehicle, equipment, vendor and overhead costs);
(4) Revenue information for each air ambulance base (e.g., revenue from paid air ambulance transports by payor type, patient cost sharing, or patient self-pay); revenue from other sources including, but not limited to contracts with facilities such as hospitals, prisons, and nursing homes); and
(5) Transport information for each air ambulance transport during the reporting period, (e.g. date of service, billing NPI information, CPT or HCPCS code information, air ambulance base, loaded miles, pick-up zip code and drop-off zip code, duration of flight, whether the transport was emergent or non-emergent, among other details.)

The Departments and OPM plan to publish a proposed information collection notice, which will provide additional technical details for required reporting. They intend to specify that plans and issuers would not need to submit the reports if they did not receive claims or make or expect to make payments for air ambulance services with respect to the reporting period.

The Departments note that they plan to take precautions to preserve the confidentiality of claims-level data and will collect only the elements needed to produce the statutorily required report.

HHS seeks comment on the calendar year as the reporting period, information on the time it typically takes payors to adjudicate and pay claims for air ambulance services by participating or nonparticipating providers of air ambulance services, the proposed data elements, the appropriate levels for reporting the data elements (regional/corporate, base, transport), potential challenges the proposed data elements would raise, and the format for reporting. In addition, HHS seeks comment on additional data sources that may be available to inform the development of its statutorily required report in lieu of proposed data elements.

III. Reporting Requirements for Individual Health Insurance

HHS proposes to add new subpart F to 45 CFR part 148 to describe new reporting and disclosure requirements regarding individual health insurance and STLD insurance. The No Surprises Act requires health insurance issuers offering individual health insurance coverage or STLD insurance to make disclosures to enrollees and submit reports to HHS regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

New §148.410(a) would establish the general requirements for issuers offering individual health insurance coverage or STLD insurance to make disclosures to individuals and to provide reports to HHS regarding direct and indirect compensation as further defined below.

Definitions

HHS proposes the following definitions in new §148.410(b):

- "Agent or broker" would have the meaning as in §155.20;
- "Commission schedule" is an itemized list or table that provides the commission levels paid by an issuer for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance;
- "Direct compensation" would be monetary amounts, including sales and base commissions, paid by an issuer that are attributable directly to the policy, certificate, or contract of insurance and that are paid to an agent or broker for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance;
- "Indirect compensation" would be payments by an issuer attributable indirectly to a policy, certificate, or contract of insurance to agents, brokers, and other persons for items other than sales and base commissions (for example, service fees, consulting fees, finders' fees, profitability and persistency bonuses, awards, prizes, volume-based incentives, and non-monetary forms of compensation); and
- "Policyholder" would be an individual who purchases individual health insurance coverage or STLD insurance and who is responsible for the payment of premiums.

Disclosure Requirements

An issuer would be required to disclose to all potential or new policyholders, the amount of direct and indirect compensation, including any applicable commission schedule and explanation of qualifying conditions for such payments. Disclosures would be required to be made prior to a potential policyholder finalizing their plan selection as well as on any documentation confirming an initial enrollment.

With respect to renewals, the disclosures must accompany the plan renewal notice as required in §147.106(f). Where there are not requirements for a notice of renewal, the issuer must disclose the direct and indirect compensation information with the invoice for the first premium payment for the initial coverage term and for each renewal period.

At a minimum, HHS proposes that commission schedules or other documents that detail the applicable commission levels and indirect compensation, such as bonuses be provided. The documents must clearly specify commissions paid by an issuer to an agent or broker for the plans for which the agent or broker has an appointment arrangement with the issuer, distinguish between commission payments for new enrollments and payments for renewed enrollments (if applicable), and explain the qualifying thresholds for payment. If an issuer of individual health insurance coverage or STLD insurance also offers direct or indirect compensation that is not captured by the commission schedule, the issuer must supplement the disclosure of the

information on the commission schedule with additional documentation disclosing such compensation.

HHS notes that it is not proposing a specific format for commission schedules or other documents disclosing direct or indirect remuneration. It has instead proposed the minimum standards described above. Its view is that the benefit of standardizing the format for such documents would not outweigh the costs of implementation.

Annual Reporting Requirements

Consistent with the No Surprises Act requirements, HHS proposes that issuers offering individual health insurance coverage or STLD insurance annually report to HHS prior to the start of open enrollment any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage. The required reporting would reflect both compensation arrangements between the writing agent or broker and the issuer, as well as arrangements from the issuer to the writing agent or broker involving intermediary organizations. HHS provides examples of two types of intermediary organizations: general line agencies and marketing organizations.

The requirements, codified in §148.410(d), would require reporting for the preceding calendar year, to be submitted no later than the last business day of July of the calendar year following the reporting year and would apply to contracts executed on or after December 27, 2021. For non-calendar year policies, issuers would be required to split the agent and broker compensation between the reports for two calendar years. It seeks comment on this proposal and indicates that it will provide additional guidance regarding non-calendar year policies in the final rule.

HHS expects the reporting to be similar to the data collected by the Department of Labor on compensation of insurance producers for group health plans subject to the Form 5500 reporting requirement. Reporting would be made electronically and HHS describes in the preamble the information that issuers would be required to provide for each payment recipient:

- Payor Federal Tax ID number;
- Recipient identifier type (NPN for writing agents or FTIN for payments to intermediaries);
- Recipient identifier value;
- Date of the payment;
- Direct compensation;
- Indirect compensation;
- Basis for indirect compensation; and
- Other information as specified by the Secretary.

HHS does not expect many contracts to be newly executed between the effective date of the statutory requirement (December 27, 2021) and the beginning of the first proposed reporting period but may exercise discretion and adopt a temporary policy of relaxed enforcement for required reporting on a case-by-case basis for contracts executed during this period. It also encourages states that are the primary enforcers of the requirements to adopt a similar enforcement approach.

IV. CMS Enforcement of Insurance and Provider and Facility Requirements

HHS proposes a series of substantive as well as technical and conforming changes to 45 CFR part 150 to ensure its existing enforcement authorities may be applied to oversee new responsibilities under the No Surprises Act. HHS states that the proposed revisions to this part would subject providers and facilities, including providers of air ambulance services, to CMS enforcement and oversight in certain circumstances, update existing regulations to align with industry standards, and implement CMS' authority to apply civil money penalties to providers of air ambulance services that do not submit required information.

Specifically, the amendments would ensure HHS has the ability to enforce certain new statutory requirements including:

- Health insurance issuers that offer individual health insurance coverage and issuers that offer STLD coverage are required to make annual reports regarding direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage;
- Issuers must report to the Departments certain information regarding air ambulance services and certain information regarding pharmacy benefits and drug costs;
- Issuers must submit to HHS an annual attestation of compliance with the prohibition of gag clauses on price and quality information;
- Air ambulance provider reporting requirements; and
- HHS is required to conduct audits of a sample of claims data with respect to a year (beginning with 2022) from not more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage to verify compliance with the qualifying payment amount requirements described in the No Surprises Act.

HHS explains that states have primary enforcement authority with respect to issuers that offer health insurance coverage in the individual and group markets for insurance as well as providers and facilities within their states. HHS expects that because the reporting requirements described above as required under the No Surprises Act, go to the federal government, States will not have the information necessary to enforce the provisions and therefore would largely defer to federal enforcement. The amendments described below retain the existing structure under which CMS is responsible for enforcing PHSA requirements where a state lacks authority or the ability to enforce those requirements, in which case, HHS would enforce those provisions.

A. CMS Enforcement in Group and Individual Insurance Markets

HHS proposes to amend the title of part 150 to indicate that it permits enforcement of provider and facility requirements as well as group and individual insurance requirements. The title would be amended to say "CMS Enforcement in Group and Individual Insurance Markets, *and Provider and Facility Requirements*." In addition, the statutory authorities are amended to include new No Surprises Act references.

1. Basis and Scope (§150.101)

Consistent with the changes described above, the statutory authority that provides the basis for the enforcement provisions is proposed to be modified to reference No Surprises Act requirements. In addition, HHS proposes a new paragraph to expand the scope of the enforcement provisions to include, in addition to enforcement related to group health plans and health insurance issuers, enforcement with respect to providers and facilities. The amendment would state that states have primary enforcement authority with respect to providers and facilities but CMS will enforce the requirements in states that do not enforce the requirements. In addition, it would state that CMS has primary enforcement authority over the provisions of section 106(a) of the NSA regarding requirements that air ambulance submit information to HHS.

2. Definitions (§150.103)

HHS proposes two new definitions related to enforcement of provider and facility requirements:

- "Facility" would mean a health care facility, an emergency department of a hospital, and an independent freestanding emergency department, as those terms are defined in §149.30, and any other facility subject to the requirements in Part E of Title XXVII of the PHS Act.
- "Provider" would be a physician or other health care provider as defined in §149.30, and a provider of air ambulance services as defined in §149.30.

Additional conforming amendments would add references to new surprise billing and transparency requirements to existing definitions.

3. State Enforcement (§150.201)

The title of §150.201 would be amended to add clarity. HHS proposes to change it from "State Enforcement" to "State Enforcement for Determining Whether States Are Failing to Substantially Enforce PHS Act Requirements." Additional conforming changes (with new parts as described below) and clarifying language is proposed as well.

HHS notes that under the proposed rules, a state would be the primary enforcer of PHS requirements against providers or facilities that furnish telehealth services to individuals located in the state – even when the provider or facility is located in a different state.

4. Circumstances Requiring CMS Enforcement (§150.203)

HHS proposes to add an "s" to the word "requirement" to clarify that more than one PHS requirement may be enforced.

5. Sources of Information Triggering an Investigation of State Enforcement (§150.205)

Existing rules permit CMS to investigate the status of state enforcement if information comes from State Governors or Commissioners of Insurance that a state is failing to substantially

enforce the requirements. HHS would amend these rules to permit information to come from additional sources that may also have relevant oversight authority. The amendments would permit information from chief insurance regulatory officials, officials responsible for regulations of health maintenance organizations, directors of public health or other state departments, agencies, or boards with applicable oversight authority.

6. Notice to State (§150.211)

If CMS determines that there is likely a failure of a state to enforce PHS requirements, CMS sends a notice to the appropriate state official. HHS proposes to conform this notice requirement to incorporate the new need to enforce provider and facility reporting requirements by adding to this section that in the case of providers and facilities, the notice would go to the official regulating such provider or facility.

7. Transition to State Enforcement (§150.221)

Similar to the above Notice to State amendment, CMS conforms this existing provision permitting a state to assume enforcement duties to also include enforcement with respect to providers and facilities (in addition to insurance issuers as is presently written.)

8. Basis for Initiating an Investigation (§150.303)

HHS proposes to conform this section, which describes the basis for initiating an investigation that an issuer or plan may be failing to meet a PHS Act requirement. The amendment would permit CMS to initiate a market conduct examination as well as an investigation. The title of the section would be amended to "Basis for Initiating an Investigation *or Examination*" instead of "Basis for Initiating an Investigation." The text of the section would be amended in the same manner and a new sentence would clarify that CMS may review any information that it identifies as relevant to determine if a violation of the PHS Act has occurred. In addition, the authority to gather reports from providers and facilities would be added to the existing authority to gather reports from State Insurance Departments, the National Association of Insurance Commissioners, and other Federal or State agencies.

Finally, paragraph (c) would be replaced. The present provision states that complaints may be directed to CMS regional offices. The provision is no longer necessary, according to HHS, because those offices no longer process complaints.[3] The paragraph would be replaced with a provision that describes CMS' authority to conduct a random or targeted investigation or market conduct examination to ensure compliance with PHS Act provisions.

[3] HHS describes several methods for entities or individuals to submit complaints which vary based on the type of coverage or plan in which an individual is enrolled and the substance of the complaint. They are described on CMS' webpage. 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.

HHS notes that the authority to conduct such investigations or examinations would provide for an additional enforcement tool. It is also consistent with the No Surprises Act requirement that HHS conduct audits of a sample of claims data to verify compliance with qualifying payment amounts (section 2799A-1(a)(2)(A)(ii)). Finally, HHS notes that it may use the proposed authority to conduct random or targeted investigations under this amendment to satisfy compliance with another provision of the No Surprises Act. Under that provision, group health plans and health insurance issuers are required to submit information on nonquantitative treatment limits for mental health/substance use disorder benefits. HHS is also required to request, review, and report to Congress on its findings regarding those limits.

9. Notice to Responsible Entities (§150.307)

Under existing rules, in the event of a potential violation, CMS provides a written notice to the responsible entity describing the substance of its information or complaint, providing for 30 days for the entity to respond, and stating that a civil money penalty could be assessed. HHS proposes changes to these notice requirements to update and clarify them.

Under the proposed rule, specificity is added by stating that if CMS receives information about a potential violation or initiates an investigation, it will provide a written notice. Under the amendment, the notice must:

- Describe the information that CMS received or state that the responsible entity was selected by CMS for an investigation under §150.303(c) (see amendment described above);
- Provide the date by which the entity must respond and the date by which additional information may be provided for CMS to use in evaluating compliance; and
- State that CMS may require a plan of corrective action.

The existing provision stating that a civil money penalty may be assessed is retained.

HHS explains that it is removing the 30-day timeline for response because it has determined that there are some circumstances that may require faster response. It notes that it expects to generally permit 14 days for a response but certain circumstances may require a 24-hour response. In addition, in situations where CMS requests large amounts of data, a longer response period may be provided.

10. Request for Extension §150.309

HHS proposes to amend a section that provides an option for entities to request an extension once notified that CMS intends to investigate. HHS would, consistent with the changes to the timeline for responding to a CMS notice of an investigation, replace the 30-day timeline with "the deadline provided in the notice under 150.307."

The existing provision requires the entity to show good cause for such an extension. HHS proposes to add examples of what CMS would consider good cause including when a responsible entity has limited staff resources to prepare a response or requests clarification from CMS.

11. Responses to Allegations of Noncompliance (§150.311)

HHS proposes to add a technical and conforming amendment to incorporate market conduct exams (described below) in an example of the kinds of documentation that may be provided to CMS for it to consider when assessing a civil money penalty.

12. Market Conduct Examinations (§150.313)

HHS proposes to reorganize and add to §150.313 to bring the CMS process for market conduct exams in line with industry practices. It proposes to:

- Conform the section in several places to ensure that the instructions in this section apply to the new random market conduct examinations as permitted in proposed §150.303(c).
- Add new paragraph (e) to describe the written notice that CMS must provide when initiating an examination. The notice would be required to include the same items as enumerated above in section 9 above describing §150.307.
- Add new paragraph (f) to describe the requirements for responsible entities to provide documentation to CMS and to request an extension. CMS would provide the responsible entity with an opportunity to provide additional information, and to make a written request for an extension. For an extension request, the reason for the request must be provided and good cause shown. If CMS grants the extension, the responsible entity must respond to the documentation request within the time frame specified. Failure to respond within specified time frames could result in imposition of a civil money penalty.
- Add new paragraph (g) to describe next steps for CMS upon receiving documentation submitted under paragraph (f). CMS could request additional information or documentation and specify a time frame for providing it. The entity may submit a written request to extend that time frame detailing the reason and showing good cause. If CMS grants the extension, the responsible entity must respond to the documentation request within the time frame specified. Failure to respond and provide such additional documentation to CMS within the time frame specified, or within an extended time frame, could result in CMS imposing a civil money penalty. CMS would identify and notify the responsible entity of any potential PHS Act violations and provide the responsible entity an opportunity to respond with additional information that it believes would demonstrate compliance or aid CMS in conducting the examination.
- Moves two existing provisions (presently in paragraph (e)(1) and (2)) to new (h)(1) and (2). The existing provisions require CMS to provide a draft report of market conduct examination to the responsible entity and describe the options for a responsible entity's response to the report. HHS proposes adding in new (h)(1) that the report must include the scope of the examination, the findings, and any corrective action the responsible entity would need to take. In new (h)(2) HHS would add that the responsible entity could explain any corrective actions that have been or will be added.
- Adds new paragraph (i) to require CMS to provide a final report of market conduct examination which describes:
    - The findings for each examination issue;
    - CMS' concurrence or disagreement with the responsible entity's positions;
    - Recommended corrective actions;
    - CMS' determination as to whether the corrective actions taken were sufficient;

- Whether further corrective actions are necessary; and
- Provides notice to a responsible entity if violations remain.

13. Determining the Amount of the Penalty – Mitigating Circumstances (§150.319)

HHS proposes a technical and conforming amendment to refer to notices provided under proposed §150.313(e) in a provision that describes a mitigating circumstance occurring before receipt of a notice under existing §150.307.

14. Determining the Amount of Penalty – Aggravating Circumstances (§150.321)

HHS proposes a new consideration that CMS may take into account in determining how aggravating circumstances should impact the amount of the penalty. New paragraph (d) would permit CMS to consider if the entity failed to cooperate with a CMS investigation or market conduct examination.

15. Settlement Authority (§150.325)

HHS proposes a conforming amendment to include notices provided under proposed §150.313(e) in a provision that describes the ability for CMS to settle cases described in notices provided under existing §150.307.

16. Definitions (§150.401)

HHS proposes a technical and conforming edit to add reference to a notice of proposed determination of a civil money penalty issued under the proposed §150.515 in the definition of "respondent" which presently refers to an entity that receives a notice of potential assessment civil money penalties under §150.343.

17. Filing of Request for Hearing (§150.405)

HHS proposes an edit to add reference to a notice of proposed determination of a civil money penalty issued under the proposed §150.515. This would provide providers and facilities 30 days from the date of such notice to request a hearing with an administrative law judge (ALJ) to appeal the proposed determination, aligning this time frame with the timeline provided to non-Federal governmental plans and issuers for appeals in states where CMS directly enforces PHS Act requirements.

18. Issues to be Heard and Decided by Administrative Law Judge (ALJ) (§150.417)

HHS proposes a conforming amendment to add reference to proposed §150.513 for factors an ALJ can apply to determine the reasonableness of a civil money penalty, aligning the process for administrative hearings regarding civil money penalties assessed against providers and facilities with that applicable to non-Federal governmental plans, and issuers in states where CMS directly enforces PHS Act requirements.

19. Evidence (§150.445)

HHS proposes conforming amendments to add references to proposed §§150.513, 150.505, and 150.515 to permit the ALJ to consider the same types of evidence as presently allowed in administrative hearings.

In addition, HHS proposes to add new paragraph (h) to permit the ALJ to consider the cross-examination of witnesses. HHS points out that this would conform with the right to cross-examination in existing rules regarding ALJ hearings in §150.419 and under section 1128(c)(2) of the SSA (regarding excluding certain providers from Medicare for cause).

20. Sanctions (§150.455)

HHS proposes to add to the potential sanctions the ALJ is permitted to apply for failing to comply with the regulations implementing the No Surprises Act in part 149. The added sanction would permit the judge to require payment of attorneys' fees or other costs caused by the compliance failure or by misconduct.

B. CMS Enforcement: Providers and Facilities (45 CFR part 150, subpart E)

HHS proposes new subpart E to establish enforcement processes with respect to providers and facilities subject to CMS enforcement. The proposed investigatory processes are intended to be parallel to those applicable to plans and issuers. However, a different civil money penalty process that conforms with the statutory requirements of the No Surprises Act would be applicable to providers, facilities, and providers of air ambulance services.

1. General Rule (§150.501)
The proposed section would authorize the imposition of civil money penalties against a provider or facility or provider of air ambulance services.

2. Basis for Initiating an Investigation; Injunctive Relief (§150.503)

Proposed provisions would establish the basis for CMS to initiate an investigation. The provision would:

- Permit CMS to conduct an investigation where information indicates a failure to comply with PHS Act or No Surprises Act requirements;
- Permit CMS to consider complaints, reports from plans or issuers, State Insurance Departments, Health Departments, Medical Boards, among others;
- Describes who may file a complaint including any aggrieved entity or individual who believes they were entitled under the PHS Act to some action or subject to a failure to act on the part of a provider or facility;
- Permits CMS to conduct random or targeted investigations; and
- Permits CMS to bring action in an appropriate district court.

3. Notice to Providers or Facilities (§150.505)

The section would require CMS to provide a written notice if a provider or facility is selected for an investigation and would describe the information necessary to be included in the notice: the information giving rise to the investigation, the date by with the provider or facility must respond to CMS' request for documentation (including overdue air ambulance data); that a civil money penalty may be assessed; and that CMS may require a plan of corrective action.

4. Request for Extension (§150.507)

The provision would permit a provider or facility to request an extension to respond to the notice described in §150.505. The provider or facility must detail the reason and provide good cause. If CMS grants the extension, the provider or facility would be required to respond within the specified timeframe – failure to do so could result in a civil money penalty.

5. Responses to Notice of Potential Violations (§150.509)

The provision would require CMS to review and consider all relevant documentation in determining whether to impose a civil money penalty. An extensive list of examples of documentation that a provider or facility may submit would include:

- Medical claims, bills, notice and consent forms, that indicate the provider or facility complied with the requirement;
- Any other evidence that refute the allegation of noncompliance;
- Evidence that the provider did not know or could not have known of the violation and any corrective action taken;
- Documentation of internal policies or procedures to ensure compliance
- Records of previous compliance; and
- Good faith efforts to submit missing information including implementation of a corrective action plan.

6. Liability for Penalty (§150.511)

HHS proposes to codify the statutory requirement that no civil money penalty may be imposed unless the action is commenced within 6 years of the date of the violation.

7. Amount of penalty (§150.513)

HHS proposes to codify permission for HHS to impose a civil money penalty in an amount not to exceed the sum of $10,000 per violation if a provider or facility is found to be in violation of a PHS Act requirement; or the sum of $10,000 if a provider of air ambulance services fails to submit required data.

In determining the amount of the penalty CMS would consider:

- The nature of claims of noncompliance and the circumstances;
- The degree of culpability of the provider or facility;
- The provider or facility's history of prior violations;

- The frequency of the violation, including whether it is an isolated occurrence, represents a pattern, or is widespread;
- The level of financial and other impacts on affected individuals; and
- Other matters as justice may require.

For every violation subject to a civil money penalty, if there are mitigating circumstances, the penalty could be set at an amount below the statutory maximum to reflect those circumstances. Mitigating circumstances would include:

- The provider or facility's record of prior compliance or complaints;
- The gravity of the violation; and
- Whether or not the violation was an isolated occurrence.

Likewise, aggravating circumstances could permit CMS to set the penalty close to the maximum permitted. Aggravated circumstances would include:

- A pattern of widespread occurrence;
- If the violation(s) resulted in significant financial and other impacts on the average affected individual(s), plan or issuer; and
- If the provider or facility does not provide documentation showing that substantially all of the violations were corrected.

CMS would be permitted to waive a penalty under certain circumstances:

- If the provider or facility does not knowingly violate, and should not have reasonably known it violated a requirement as long as the provider or facility withdraws any erroneous bill and, if necessary, reimburses the plan or enrollee, within 30 days of the violation plus interest. HHS proposes using the rate it customarily uses for overpayments and underpayments.
- In the case of a provider of air ambulance services that submits only part of the data required if such provider demonstrates a good faith effort in working with HHS to submit missing information.

CMS would be permitted to settle any issue or case or compromise on any penalty imposed under §150.515 including to account for a significant financial hardship.

8. Notice of Proposed Determination (§150.515)

HHS would incorporate the following statutory requirements when imposing civil money penalties:

- To initiate a penalty, CMS must serve notice of the action consistent with Rule 4 of the Federal Rules of Civil Procedure;
- The notice must include:
    - A description of the requirements that CMS believes were violated,
    - A description of the complaint or other information that prompted the investigation,
    - The amount of the proposed penalty,
    - Any aggravated or mitigating circumstances considered in determining the penalty, and

- Instructions for the provider's or facility's response to the notice including the right to request a hearing within 30 days of receipt.

9. Hearing (§150.517)

Consistent with statutory requirements, HHS proposes to provide that the requirements specified in §§150.401 – 150.457 apply to hearings under this subpart. Those provisions include the requirement that CMS provide written notice and an opportunity for an adverse determination to be made on the record after a hearing, and the right to the provider or facility to be represented by counsel, present witnesses, and to cross-examine witnesses. In addition, the official conducting the hearing is permitted to sanction a person for failing to comply with an order or procedure, failing to defend an action or other misconduct that interferes with the hearing. If a provider or facility fails to exercise a right to a hearing, the proposed penalty becomes final.

10. Failure to Request a Hearing (§150.519)

HHS would specify that if a provider or facility does not request a hearing within 30 days of the notice (as required in §150.515), CMS may assess the proposed civil money penalty and the provider or facility would have no right to appeal the penalty. Under proposed §150.405(b) a provider or facility may be permitted to show good cause for not timely exercising its right to a hearing.

11. Collateral Estoppel (§150.521)

HHS proposes to codify the statutory requirement that a provider or facility that requests a hearing may not deny the essential elements of a criminal offense if that provider or facility has been convicted of a Federal crime charging fraud or false statements.

12. Judicial Review (§150.523)

HHS would establish the right of a provider or facility to obtain review by the ALJ in the U.S. District Court of Appeals of a final decision imposing a civil money penalty.

13. Notice to Other Agencies (§150.525)

Whenever a penalty becomes final, CMS would be required to notify the following organizations and entities: the appropriate state or local medical or professional association, the State Department of Health, the state or local licensing or organization, and the utilization and quality control peer review organization. The Secretary may also notify as appropriate, the State Department of Insurance, the Attorney General, the Secretary of Labor, the Secretary of Treasury or OPM.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, the Departments are required to solicit public comment on its collection of information before its submission to OMB for review and approval,

including the need for the information collection, the accuracy of its estimates, the quality of information collected, and recommendations to minimize the collection burden. Table 7 of the proposed rule preamble provides a summary of the annual burden estimates for information collection requirements.

A. ICRs Regarding Disclosure of Agent and Broker Compensation

HHS estimates that 1,298 issuers in the individual market and 26 issuers of STLD insurance coverage would need to implement disclosure requirements with respect to agent and broker compensation prior to and when individuals enroll in coverage.

- One-time costs. HHS expects that issuers will need a lawyer to review the disclosures and prepare instructions to implement the requirements. HHS estimates a burden of 2 hours for each issuer for a total of 2,648 hours across all insurers and a total of $379,141. In addition, agents and brokers, who are likely to communicate the information on behalf of issuers, would incur costs for reviewing the requirements. A total of 55,541 agents or brokers are estimated to need 27,770 hours for a total cost of approximately $1.8 million. Printing costs incurred is estimated to be $333,246. The summary of the estimated one-time costs for the provision are in Table 2 of the published proposed rule.
- Ongoing costs for disclosure included with enrollment materials. Issuers of individual health insurance coverage are estimated to each take 183 hours to provide commission schedules and supplemental documents to individuals at a cost of $7,113 annually. For all issuers, those costs total $9.2 million. Printing costs for the materials is estimated to add $855,347 for a total of $10 million per year. Likewise, issuers of STLD plans are expected to require a total of 256 hours at a cost of $9,950 per issuer per year. For all issuers, those costs total $258,695. Printing costs are expected to add $922 for a total cost of $259,616 annually.

B. ICRs Regarding Issuer Reporting of Agent and Broker Compensation to HHS

Table 4 provides the estimated ongoing costs of reporting agent and broker compensation to HHS. HHS estimates that each issuer would incur an annual burden of 50 hours with a cost of $4,277. Together for all issuers, HHS estimated total annual ongoing costs of $5.7 million.

C. ICRs Regarding Air Ambulance Reporting Requirements for Group Health Plans and Health Insurance Issuers

Issuers, FEHB carriers and third-party administrators would incur one-time burden to make information technology (IT) changes necessary to meet air ambulance reporting requirements as well as continuing costs for each year that reporting is required. One-time costs are expected to comprise 48 hours for each issuer, FEHB carrier or TPA at a cost of $4,923; totaling $3.6 million in 2022. The ongoing costs of submitting the data for each of the 2022 and 2023 plan years is estimated to require each issuer, FEHB carrier or TPA to incur a burden of 12 hours, costing $1,145 each; totaling .8 million in each of 2023 and 2024. In Table 5, which summarizes those costs, only 45% of those amounts are displayed because the table reflects only HHS' share of the

burden and excludes DOL, Treasury and OPM's shared burden based on their shared jurisdiction.

D. ICRs Regarding Air Ambulance Reporting Requirements for Providers of Air Ambulance Services.

HHS estimates one-time burden costs for 75 air ambulance services providers in 2022 for IT changes. Those costs are estimated to comprise 400 hours per provider at a cost of $40,997. Those amounts would total $3.1 million across all providers. In addition, the ongoing costs of collecting and formatting the data for each of 2022 and 2023 are estimated to cost each provider a total of $1,794 for 20 hours at a total across all air ambulance providers of $134,538 in each of 2023 and 2024. Those costs are summarized in Table 6 in the published proposed regulation.

VI. Regulatory Impact Analysis

The Departments and OPM have examined the effects of the proposed rules pursuant to Executive Order 13563, Executive Order 12866, the Regulatory Flexibility Act and other authorities. They have determined that the IFC is "economically significant" within the meaning of Executive Order 12866 because they are likely to raise novel legal or policy issues arising out of legal mandates. They are not expected have economic impacts of $100 million or more in any one year. Accordingly, the Departments provide a qualitative discussion of the potential costs, benefits, and transfers associated with these rules. They note that they are unable to quantify many of the benefits and costs.

Table 8 (Accounting Statement) summarizes the benefits and intended outcomes. In addition, the discussion provides additional information about the expected benefits and costs of the provisions including:

- The additional transparency regarding the number of air ambulance providers that participate in insurer networks and the number and location of air ambulance bases would enable assessment of the availability of services and competition in the marketplace. The Secretary of Transportation may be able to use the information to monitor unfair or deceptive practices as well as unfair methods of competition in the air ambulance service market.
- Disclosures by health insurance issuers of individual plans and STLD plans will improve consumers' awareness and enable them to take this information into account in making insurance choices. HHS analysis of the information will enable it to monitor marketing operations and practices and to inform future policy decisions.
- HHS expects to conduct approximately 200 investigations per month of potential violations of PHS Act provisions – a total of 2,400 per year beginning in 2022. Each investigation is expected to cost a responsible entity $354 with a total annual cost of $850,320. HHS is unable to estimate the number of entities for which penalties would be assessed, assessed penalties that are appealed, the outcomes of appeals, or the associated costs.
- Costs to the Federal government for new IT systems and data collection and additional enforcement activities is estimated to be $4 million in 2021, $20.3 million in 2022, $22.2 million in 2023, $18.3 million in 2024 and $18.4 million in 2025.