HAYS COMPANIES

Final Health Plan Transparency Regulations Issued

By: Scott Wold, Assistant Vice President of Regulatory and Legislative Strategy

In late October, the DOL, IRS, and CMS issued final regulations (referred to in this article as the "Health Plan Transparency Regulations" or the "Regulations") implementing two significant health plan pricing transparency initiatives. These regulations further the Trump Administration's goal of improving health care pricing and quality transparency, a goal previously announced in an Executive Order issued in June 2019. The Regulations build on previously issued regulations addressing hospital price transparency. According to a Fact Sheet released by CMS along with the final regulations, the Regulations "will empower consumers to shop and compare costs between specific providers before receiving care" and "will drive innovation, support informed, price-conscious decision-making, and promote competition in the health care industry."

The purpose of this article is to identify who is impacted by the final regulations, describe the actions required by the final regulations, and identify some steps employers should be taking to prepare for compliance.

WHO MUST COMPLY WITH THE HEALTH PLAN TRANSPARENCY REGULATIONS?

The Regulations apply to group health plans (including employer-sponsored plans, multi-employer (Taft-Hartley) plans, and MEWAs) and to health insurance issuers providing coverage in the group and individual insurance markets. While the term "group health plan" is generally a very broad term, for purposes of the Regulations, it is generally limited to medical plans. The Regulations indicate group health plans that are HIPAA excepted benefits (e.g., most dental and vision plans, on-site medical clinics, etc.) and account-based health plans (e.g., health FSAs, HRAs, ICHRAs, etc.) are not subject to the requirements.

Caution: Dental and vision benefits are treated as an excepted benefit only if they are either (1) offered under a separate policy, certificate, or contract of insurance; or (2) they are not an integral part of a group health plan, which is generally true if participants may decline coverage for the benefit or if claims for the benefits are administered under a contract separate from claims administration for any other benefits under the plan. When a plan provides dental or vision benefits that do not qualify as excepted benefits, the plan will be required to make the required disclosures with respect to the dental and/or vision benefits.

Furthermore, the Regulations do not apply to grandfathered health plans (i.e., plans that have not made changes to plan design or premium sharing since March 23, 2010, in excess of permitted amounts as described in the Final Rules for Grandfathered Plans, which were published in the Federal Register on November 18, 2015). The Regulations are issued pursuant to Section 2715A of the Public Health Service Act (PHSA). Section 2715A does not apply to health plans that are grandfathered plans under the Patient Protection and Affordable Care Act (PPACA). All references to health plans and group health plans in the remainder of this article are references to non-grandfathered plans unless otherwise noted. For additional information about grandfathered plans, see Grandfather Health Insurance Plans.

Although the Regulations will apply to both the plan and the issuer when a group health plan is fully-insured, if the plan and the issuer enter into a written agreement pursuant to which the issuer agrees to fulfill the plan's disclosure obligations under the Regulations, then the issuer is solely responsible for the compliance obligations, and the plan will have no liability if the issuer fails to comply. Given the fact the Regulations were issued about one month ago, at this point it is unknown whether:

1. Issuers will be willing to undertake sole responsibility for complying with the Regulations
2. If so, what the issuers might want in return for doing so.

For self-insured group health plans (including level-funded arrangements with stop loss), the employer sponsoring the plan may contract with the TPA that administers the plan to provide the disclosures required by the Regulations. However, in this case, the plan will retain ultimate responsibility in the event the TPA fails to comply with the Regulations.

WHAT ACTIONS ARE REQUIRED BY THE HEALTH PLAN TRANSPARENCY REGULATIONS?

The Regulations impose the following two disclosure obligations on group health plans and issuers of health insurance:

DISCLOSURES TO PARTICIPANTS

The Regulations require plans and issuers to disclose certain cost-sharing and pricing information to participants, beneficiaries, and enrollees (referred to herein collectively as "participants") upon request. The preamble to the Regulations clarifies that these disclosures must be made only to individuals actually covered by the plan (and their authorized representatives). Disclosures need not be made to eligible employees who are not enrolled in the plan.

The required disclosures must be made through a self-service tool available on an internet website (e.g., the insurance issuer's, TPA's, or plan sponsor's website). In addition, the required information must be provided in paper form at no cost upon request, in which case the information must generally be mailed to the participant no later than two (2) business days after receipt of the request.

The information that must be disclosed consists of the following seven (7) elements:

1. An estimate of the participant's cost-sharing liability (in dollars) under the plan for a covered item or service furnished by a provider or providers. Covered items and services include all items and services for which benefits are available under the plan including prescription drugs and durable medical equipment. Estimates must be based on in-network rates, out-of-network allowed amounts, and the participant's accumulated amounts.

2. Amounts the participant has already accumulated toward the plan's deductible, out-of-pocket maximum, and treatment limitations.

3. The in-network rate, which includes the following information as applicable under the plan: (a) the negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service (which must be disclosed even if it is not the rate the plan uses to calculate cost-sharing liability); and (b) the underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

4. Out-of-network allowed amount or any other rate that provides a more accurate estimate of the amount a plan will pay for the covered item or service, reflected as a dollar amount. This element applies only if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider.

5. If a participant requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

6. If coverage of a specific item or service is subject to a prerequisite, notice that the prerequisite applies. The Regulations include the following exhaustive list of prerequisites: concurrent review, prior authorization, and step-therapy or fail-first protocols. It is not necessary to include a complete description of the applicable prerequisite.

7. A notice that includes certain specific information (listed in the Regulations) regarding the disclosure. For example, the notice must state that the actual charges for a participant's covered item or service may be different from the estimate of cost-sharing liability provided by the self-service tool. The agencies have provided model language for this notice but plans and issuers are not required to use it.

Note: Although the notice will include a disclaimer about the accuracy of the participant's cost-sharing obligations with respect to a covered item or service, there is a concern whether participants will be able to enforce the estimate if the actual cost differs. The preamble to the Regulations states that the regulatory agencies "are of the view that it would not be prudent to hold plans and issuers liable to the exact estimate that is provided." That position, however, is not necessarily binding on participants and the courts. The content of the disclaimer and ensuring it is read by the participant will likely be very important.

The self-service tool must be designed to provide real-time responses that are accurate as of the date on which the request is made. It must allow participants to search for information for a covered item or service by a specific in-network provider, by all in-network providers, or by out-of-network providers by inputting certain information about the item/service and provider.

DISCLOSURES TO THE PUBLIC

The Regulations also require plans and issuers to disclose certain pricing information to the public. This information must be made available in three separate machine-readable files. The data files must be displayed in a standardized format specified in the Regulations. Plans and issuers are required to provide updates to the files monthly. As with the disclosures to participants described above, the files must be made available on an internet website.

Each machine-readable file must include a specific set of data.

- One file must include the rates negotiated between the plan/issuer and in-network providers for all covered items and services.
- Another file must include data showing the historical payments to, and billed charges from, out-of-network providers.
- The third file must include data reflecting the in-network negotiated rates and historical net prices for all covered prescription drugs by plan or issuer at the pharmacy location level.

BY WHAT DATE MUST HEALTH PLANS COMPLY WITH THE NEW REQUIREMENTS?

Recognizing that plans and issuers will need time to set up systems to comply with the disclosure requirements, the Regulations implement them in phases as follows:

- Starting with the first plan year beginning on or after January 1, 2022, group health plans and issuers must comply with the requirement to make pricing information available to the public.
- Starting with the first plan year beginning on or after January 1, 2023, group health plans and issuers must comply with the requirement to disclose cost-sharing and pricing information to participants upon request, but only with respect to 500 specific services and items. The 500 services and items are listed in a table in the preamble to the Regulations, and the agencies intend to publish the list on a public website.
- Starting with the first plan year beginning on or after January 1, 2024, group health plans and issuers must comply with the requirement to disclose cost-sharing and pricing information to participants upon request with respect to all services and items covered by the plan or policy.

IS THERE A CHANCE THAT THE HEALTH PLAN TRANSPARENCY REGULATIONS WILL BE REPEALED OR VACATED BEFORE THEY BECOME EFFECTIVE?

The Regulations could be rendered moot by the forthcoming Supreme Court decision in the *Texas v. California* case, which is expected to be released in early Spring 2021. Because the authority for the Regulations comes from a provision in the PHSA added by PPACA, if the Supreme Court rules that the entire law is unconstitutional, then the Regulations will become ineffective.

It is also possible that the Biden Administration could modify or repeal the Regulations through regulatory action. However, transparency generally has bipartisan support in Congress, so the likelihood of significant changes to the Regulations by the Biden Administration seems uncertain.

Finally, there is a distinct possibility the Regulations will be challenged through litigation. The hospital pricing transparency regulations have already resulted in litigation that is working its way through the courts. Similar litigation could be initiated by challenging the validity of these Regulations.

WHAT OTHER ISSUES ARE RAISED BY THE HEALTH PLAN TRANSPARENCY REGULATIONS?

The Regulations raise several other issues that may impact group health plans and their sponsors. These issues include:

- **MLR Rebates:** The regulations modify the MLR rebate rules contained in PPACA effective for the 2020 MLR reporting year. Specifically, the MLR rules have been modified to, as stated in the preamble, permit insurance issuers "to receive credit in their MLR calculations for savings they share with enrollees that result from the enrollees shopping for, and receiving care from, lower-cost, higher-value providers."
- **Impact on Cost of Coverage:** There seems to be little doubt that compliance with the Regulations will increase costs, and those costs will be passed on to employers and insureds in the form of higher premiums and administrative fees.
- **HIPAA Privacy and Security Concerns:** The Regulations acknowledge that information provided to participants through the self-service tool will constitute protected health information (PHI) and that HIPAA covered entities (i.e., group health plans and health insurance issuers) will need to ensure that the self-service tool protects the privacy and security of that PHI.
- **Contractual Obligations Regarding Proprietary Information:** Some comments regarding the proposed regulations raised concerns that in order to comply with the disclosure requirements plans and issuers might be required to violate certain contractual provisions that

require them to maintain the confidentiality of proprietary information. The regulatory agencies brushed aside those concerns, stating that many such contracts already contain exceptions when the disclosure of the information is required by law (which would be the case here) and they were leaving it to plans, issuers, and providers "to avoid contract terms that would prohibit or frustrate either party's compliance with the final rules."

- **Enforcement and Penalties:** In general, where a plan (rather than an insurance issuer) is responsible for complying with the Regulations, a failure to comply will result in excise taxes under Section 4980D of the Internal Revenue Code (for private employers and church plans) or Section 2723 of the PHSA (for governmental plans). The amount of the excise tax is "$100 for each day for each individual with respect to which such a failure occurs." Sections 4980D and 2723 include provisions in which the excise taxes can be reduced or avoided in some circumstances.

  In addition, the Regulations include several provisions intended to limit potential liability for plans that are attempting to comply with the new requirements. Specifically, the Regulations provide that there is no violation if:

  - The plan makes an error or omission in a disclosure so long as the plan acted in good faith and with reasonable diligence and it corrects the error or omission as soon as practicable.
  - The internet website through which the plan makes the required disclosure is temporarily inaccessible so long as the plan acted in good faith and with reasonable diligence, and it makes the information available as soon as practicable.
  - The plan reasonably relies on information it has obtained from another party even if that information is incomplete or inaccurate so long as the plan does not know, or reasonably should not have known, that the information was incomplete or inaccurate.

WHAT STEPS SHOULD OUR CLIENTS TAKE NOW TO PREPARE FOR COMPLIANCE WITH THE HEALTH PLAN TRANSPARENCY REGULATIONS?

For calendar year plans, the first compliance date is a little over one year away. Accordingly, plan sponsors need to begin preparing to comply now. Although, as a practical matter, plan sponsors will need to rely on their insurance issuers and TPAs to do much of the work, there are some steps plan sponsors should take, including the following:

- Identify which plans are subject to the disclosure requirements. For example, is the employer's medical plan grandfathered and, therefore, exempt from complying with the Regulations? Are the employer's dental and vision plans HIPAA excepted benefits and, therefore, exempt from complying with the Regulations?

Note: To the extent the employer's medical plan is currently grandfathered and the employer is considering changes to the plan that would cause a loss of grandfathered status, the need to comply with the Regulations will be a new factor to consider when weighing the advantages of maintaining grandfathered status.

- Begin negotiating with issuers and TPAs to undertake compliance with the Regulations on behalf of the plan.
- Evaluate the impact of implementation of the web-based self-service tool on the plan's HIPAA privacy and security policies and procedures.
- Review applicable contractual language regarding disclosure of proprietary information to determine whether such language must be modified to enable compliance with the Regulations.

Contact

Visit us online or send us a message to learn more about the Hays Difference and our service offerings.

www.hayscompanies.com | info@haysccompanies.com