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Trump Administration Issues COVID-19 Vaccine and Transparency Rules

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In late October, the Trump Administration, through the Departments of Health and Human Services ("HHS"), the Treasury, and Labor ("Departments"), issued two different rules — one implementing the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") COVID-19 vaccine mandate, and the other implementing the Affordable Care Act's transparency mandate. These rules were part of a rush of health care regulations pushed out the door in the last few months of the Trump Administration.

On October 28, 2020, the Departments released an interim final rule with request for comment ("IFC") that, among other things, amends current regulations regarding coverage of preventive health services to implement the requirement under the CARES Act that group health plans and health insurance issuers provide "rapid coverage" of services and vaccines related to the prevention of COVID-19. The IFC also implements provisions in the CARES Act that require providers of COVID-19 diagnostic tests to publish the cash price for such tests and establishes a scheme to enforce those requirements.

The next day, on October 29, the Departments released a final rule requiring group health plans and health insurance issuers in the individual and group markets to disclose certain cost-sharing information ("Transparency Final Rule" or "Final Rule"). The Final Rule was issued pursuant to the Affordable Care Act and is part of the Trump administration's efforts to promote health care price transparency and require group health plans and issuers to disclose a "substantial amount" of information to provide transparency in coverage. The Final Rule establishes two separate requirements for the disclosure of cost-sharing and pricing information: Internet Self-Service Tool with Cost-Sharing Information and Public Disclosure of Pricing Information on Machine-Readable Files.

While these two rules are not substantively linked, they are among the last rules issued by the Trump administration that will affect private coverage. While the Biden Administration may undo many of the Trump Administration's policies, it is not nearly so clear that they will rescind or replace either of these rules, though the Biden administration may issue another rulemaking or sub-regulatory guidance affecting the scope of the rules. We note that, in particular, the Transparency Final Rule's

requirement to publicly disclose in-network contract rates with providers is controversial, particularly with health insurers that believe the public disclosure of contracted rates for network providers is both anti-competitive and very burdensome.

The summary below addresses both the IFC and the Transparency Final Rule by providing important background information and an overview of their provisions.

IFC Addressing Coverage of COVID-19 Preventive Services and Provider Publication Requirements

The IFC has two primary areas of impact: *first*, provision of "rapid coverage" of services and vaccines related to the prevention of COVID-19; and *second*, requirements concerning COVID-19 diagnostic tests and publication of the prices providers charge for those tests. We address each in turn.

A. Rapid Coverage of Preventive Services and Vaccines

Section 3203 of the CARES Act requires group health plans and health insurance issuers to cover without cost-sharing any "qualifying coronavirus preventive service." In the Act, Congress specified that the coverage should be provided pursuant to section 2713(a) of the Public Health Service Act ("PHS Act"), including its implementing regulations ("Preventive Services Regulations"). The IFC makes several important clarifications and codifications: (1) it clarifies the meaning of a "qualifying coronavirus preventive service;" (2) it clarifies which related items and services must also be covered; (3) it imposes an out-of-network coverage requirement; (4) it codifies the rapid implementation timeline provided under the CARES Act; and (5) it provides a sunset for provisions of the IFC.

Qualifying Coronavirus Preventive Service. The Act defines a qualifying service as "an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019" and has a rating of "A" or "B" in the recommendation of the United States Preventive Services Task Force ("USPSTF") or is recommended by the Advisory Committee on Immunization Practices ("ACIP") of the Centers for Disease Control and Prevention ("CDC"). Substantively, this matches the definition of preventive services under the PHS Act; however, the Preventive Services Regulations specify that only immunizations recommended by ACIP for "routine use" be covered without cost sharing. Recommendations are considered to be for routine use if they are listed on the CDC Immunization Schedule.

The definition of qualifying coronavirus preventive service under the IFC is consistent with the definition under the CARES Act. However, unlike preventive services generally covered without cost sharing under the PHS Act and the Preventive Services Regulations, qualifying coronavirus preventive services are not limited to COVID-19 immunizations recommended by ACIP for "routine use." This is so, according to the Departments, because a qualifying coronavirus preventive service might not be recommended for routine use in the immediate future. Accordingly, plans and issuers must cover such services without cost sharing even if *not* listed for routine use on the CDC Immunization Schedule.

Related Items and Services. The Departments clarify that under the Preventive Services Regulations and the IFC, group health plans and health insurance issuers must cover, without cost sharing, "items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately." The Departments note that since a medical professional will generally need to administer a recommended immunization, plans and issuers must cover, without cost sharing, the immunization *and* its administration, regardless of how it is billed or whether it requires multiple doses. The Departments also clarify that plans and issuers must cover, without cost sharing, the *administration* of a qualifying immunization even in instances where a third party (such as the federal government) pays for the actual immunization.

Out-of-Network Coverage. Under the Preventive Services Regulations, plans and issuers are not required to cover preventive services out-of-network or waive cost-sharing out-of-network if the plan's in-network providers offer such service. By contrast, the IFC requires that plans and issuers cover, without cost sharing, a qualifying coronavirus preventive service, regardless of whether an in-network or out-of-network provider delivers the service. The Departments reason that newly developed coronavirus-related preventive services may not be widely available, so this requirement is designed to "ensure full access to and the widespread use of qualifying coronavirus preventive services."

To ensure that the benefit is "meaningful," the Departments specify that plans and issuers must reimburse out-of-network providers "in an amount that is reasonable, as determined in comparison to prevailing market rates for such service." For example, the Departments consider the amount that would be paid under Medicare for the item or service to be reasonable.

Rapid Coverage. Under the CARES Act, the requirement to cover qualifying coronavirus preventive services without cost share takes effect 15 business days after the date the recommendation is made. The IFC codifies this timing requirement. This is much shorter than the timeline generally provided under the PHS Act and the Preventive Services Regulations, which requires plans and issuers to cover recommended preventive items and services beginning the year that follows the year in which the recommendation was made.

Sunset. Certain provisions of the IFC will sunset at the end of the COVID-19 public health emergency. Specifically, the definition of qualifying coronavirus preventive services that requires covering immunizations not yet approved for routine use, the requirement to provide out-of-network qualifying coronavirus preventive services without cost share, and the 15-day rapid coverage timeline will not apply to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency, as per the IFC.

B. Provider Publication Requirements

Section 3202(a) of the CARES Act requires group health plans and issuers providing coverage of items and services described in the Families First Coronavirus Response Act (the requirement to cover COVID-19 testing and certain items and services without cost sharing) to reimburse providers of COVID-19 diagnostic testing at the same rate as previously negotiated before the public health emergency. If a plan or issuer did not have an existing, negotiated rate with a provider before the public health emergency, the plan or issuer must pay the provider's cash price for the test as posted by the provider on a public website (or the plan or issuer may negotiate a lower rate).

Under section 3202(b)(1) of the CARES Act, each provider of a COVID-19 diagnostic test must publicize cash prices for such test on a public website. Section 3202(b)(2) of the CARES Act authorizes the Secretary of HHS to impose a civil monetary penalty ("CMP") on any provider that does not comply with the publication requirements.

The IFC adopts policies that implement the publication requirement, including specifying the penalties for non-compliance with the cash price posting requirements. Specifically, the IFC provides that the Centers for Medicare & Medicaid Services ("CMS") may impose a CMP on a provider that it identifies as non-compliant with the requirements of the IFC and that fails to respond to CMS' request to submit a corrective action plan ("CAP") (or to comply with the requirements of a CAP that was previously approved by CMS). The maximum daily CMP amount to which a provider may be subject is $300. This is true even if the provider is in violation of multiple discrete requirements of the IFC. A provider must pay the CMP in full within 60 calendar days after receiving notice of the CMP from CMS.

The regulations were effective on November 6, 2020. To be given consideration, comments must have been received within 60 days of the effective date, or January 4, 2021. It is possible there will be additional guidance on the COVID-19 preventive services requirement following the Departments' review of the submitted comments.

Transparency in Coverage Final Rule, Requiring Group Health Plans and Issuers to Disclose "Substantial Amount" of Cost-Sharing Information

As the Preamble of the Transparency Final Rule acknowledges, group health plans and issuers are required to disclose a "substantial amount" of information to provide transparency in coverage. However, in a welcome departure from the proposed rule, the Final Rule's requirements are phased in over three years, with some requirements applying for plans years beginning in 2022, others in 2023, and all requirements effective for plan years beginning in 2024.

The Final Rule establishes two separate requirements—Internet Self-Service Tool with Cost-Sharing Information *and* Public Disclosure of Pricing Information on Machine-Readable Files.

Internet Self-Service Tool with Cost-Sharing Information. Starting in 2023, the first requirement mandates that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees, upon request, through an internet-based self-service tool, certain cost-sharing information for a covered item or service from a particular provider.

Plans and issuers must make cost-sharing information available for 500 items and services identified by the Departments for plan years beginning on or after January 1, 2023, and must make cost-sharing information available for *all* covered items and services for plan years beginning on or after January 1, 2024.

Public Disclosure of Pricing Information on Machine-Readable Files. The second requirement directs plans and issuers to disclose to the public, through three machine-readable files: (1) all applicable rates for in-network providers for each covered item or service; (2)

allowed amounts and billed charges for covered items or services furnished by out-of-network providers; and (3) pricing information for prescription drugs. This requirement applies to plan years beginning on or after January 1, 2022.

This final regulation applies to group health plans (including self-funded plans) and health insurance issuers in the group and individual markets, including "grandmothered" plans. Conversely, the final regulation does *not* apply to grandfathered health plans, health reimbursement arrangements or other account-based group health plans, excepted benefits and short-term, limited duration insurance.

A. Background

On June 24, 2019, President Trump issued an executive order, entitled "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (the "Executive Order"). The Executive Order directed the Departments to issue an advance notice of proposed rulemaking soliciting comments on a proposal that would require health care providers, health insurance issuers, and self-insured group health plans to provide information about expected out-of-pocket costs for items or services to patients before they receive care.

On November 27, 2019, the Departments published a proposed rule in response to President Trump's June 24, 2019 Executive Order (the "Proposed Rule").

The Final Rule implements section 2715A of the PHS Act and section 1311(e)(3) of the Affordable Care Act, which has already been implemented for qualified health plans on the Exchange.

B. Disclosure of Cost-Sharing Information to Participants, Beneficiaries, or Enrollees Through Internet Self-Service Tool

The Final Rule require group health plans and health insurance issuers to disclose certain cost-sharing information upon the request of a participant, beneficiary, or enrollee (or his or her authorized representative) through an internet-based, self-service tool or in paper form.

Plans and issuers must make cost-sharing information available for 500 items and services (identified by the Departments in a table in the Preamble) for plan years beginning on or after January 1, 2023 and must make cost-sharing information available for all items and services for plan years beginning on or after January 1, 2024.

1. Cost-Sharing Information that Must Be Provided

The Final Rule requires that plans and issuers must disclose seven content elements through an internet-based, self-service tool to a participant, beneficiary, or enrollee for a covered item or service. Plans and issuers must disclose actual data relevant to an individual's cost-sharing liability that is accurate at the time the request is made.

The seven content elements are as follows:

- **An estimate of cost-sharing liability** for a requested covered item or service provided by a provider (including prescription drugs) based on the data elements that follow.
- **Accumulated amounts** incurred to date (e.g., deductible, out-of-pocket limits, and visit limits).
- **In-network rate** comprised of the following elements, as applicable to the plan's or issuer's payment model:
  - **Negotiated rate (reflected as a dollar amount) for an in-network provider** for the requested covered item or service.
  - **Underlying fee schedule rate (reflected as a dollar amount)** for the requested covered item or service (only where that rate is different from the negotiated rate).
- **Out-of-network allowed amount**, or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for an out-of-network provider.
- **Items and services content list.** If the item or service for which a request is being made is subject to a bundled payment arrangement, a list of the items or services for which cost sharing information is being disclosed.

- **Notification that coverage of a specific item or service is subject to a prerequisite** (*e.,* concurrent review, prior authorization, and step-therapy or fail-first protocols).
- **Disclosure notice.** A disclosure notice that communicates certain information in plain language, including several required disclosures. The Departments are expected to issue final model language that plans and issuers can use, but are not required to use, to satisfy this requirement.

2. Internet-Based Self-Service Tool

The Final Rule requires that the cost-sharing information noted above be made available through a free self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request.

The self-service tool must allow users to search for both (1) cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers, and (2) an out-of-network allowed amount, percentage of billed charge, or other rate for a covered item or service provided by out-of-network providers, in either case by the user inputting:

- A billing code (*g.*, CPT Code) or a descriptive term (*e.g.*, rapid flu test), at the option of the user;
- For in-network providers, the name of the in-network provider; and
- Other relevant factors used by the plan or issuer to determine the applicable cost-sharing amount.

Users must be able to use the tool to refine and reorder search results based on geographic proximity of providers, and the amount of estimated cost-sharing liability for the covered item or service.

The Final Rule also requires that the requested information be provided in paper form, upon request and without a fee, and that it be mailed no later than two business days after the request is received. The Final Rule permits the group health plan or issuer to limit the number of providers with respect to which cost-sharing information is provided to no fewer than 20 providers per request. The Final Rule also provides that to the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or e-mail), plans and issuers may provide the disclosure through another means, but must still provide the information no later than two business days after the request is received.

3. Special Rule to Prevent Unnecessary Duplication

The Final Rule includes a special rule to streamline the provision of the required disclosures and avoid unnecessary duplication of the disclosures with respect to group health coverage. This special rule includes two parts: (1) for insured group health plans where a health insurance issuer offering coverage in connection with the plan has agreed to provide the required information (in this case, the issuer will be liable for compliance); and (2) for plans and issuers that contract with a third party to provide the information on their behalf (in this case, the plan or issuer will continue to be liable for compliance). For plans and issuers that contract with a third party to provide the information on their behalf, the Departments note that, "to the extent permitted under other Federal or state law," a plan or issuer may include in the agreement for the other party to indemnify the plan or issuer in the event the other party fails to make the full or timely disclosure required by the Final Rule.

C. Public Disclosure of In-Network Rates, Allowed Amounts, and Prescription Drug Pricing Information on Machine-Readable Files

For plan years beginning on or after January 1, 2022, the Final Rule requires a group health plan and health insurance issuer to make available on a public internet website three machine-readable files that include the following information for covered items and services:

- In-network rates (the "In-Network Rate File");
- Historical allowed amount data (the "Allowed Amount File"); and
- Prescription drug pricing information (the "Prescription Drug File").

The Final Rule requires plans and issuers to update this information on a monthly basis. The machine-readable files must be accessible free of charge, without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information such as a name or email address.

The Departments are developing technical implementation guidance for plans and issuers to assist them in developing the machine-readable files.

1. Specific Content Elements

The following content requirements apply to all three machine-readable files (except where indicated):

- For each coverage option offered by a group health plan or issuer, the name and 14-digit Health Insurance Oversight System ("HIOS") identifier, or, if the 14 digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number ("EIN");
- A billing code, which in the case of prescription drugs must be a National Drug Code ("NDC"), and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and
- In-network applicable amounts; out-of-network allowed amounts; or negotiated rates and historical net prices for prescription drugs (depending on the file).

The Final Rule requires that all three files include the provider's National Provider Identifier, tax identification number, and Place of Service Code.

The *In-Network Rate File* must disclose all applicable rates, which may include one or more of the following: negotiated rates, underlying fee schedule rates, or derived amounts. Rates must be reflected in dollar amounts, associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service, and indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

The *Allowed Amount File* must include unique out-of-network allowed amounts and billed charges with respect to covered items or services, furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file. Plans and issuers are required to omit allowed amount and billed charges data in relation to a particular provider and a particular item or service when compliance would require reporting in connection with fewer than 20 different claims for payment.

Finally, the *Prescription Drug File* must disclose both the negotiated rates and historical net prices. Both the negotiated rates and historical net prices must be reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser. The negotiated rates must be associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC. The historical net prices must be associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC. Similar to the Allowed Amount File, plans and issuers are required to omit historical net pricing data in relation to a particular NDC and a particular provider when compliance would require reporting payment of historical net prices calculated using fewer than 20 different claims for payment.

2. Special Rule to Prevent Unnecessary Duplication

Similar to the special rule for the internet-based, self-service tool disclosure requirements, the Final Rule includes a special rule to streamline the provision of the required public disclosures in machine-readable files. This special rule has three parts: (1) for insured group health plans where a health insurance issuer offering coverage in connection with the plan has agreed to provide the required information (in this case, the issuer will be liable for compliance); (2) for plans and issuers that contract with third parties to provide the information on their behalf (in this case, the plan or issuer will continue to be liable for compliance); and (3) a special rule allowing aggregation of out-of-network allowed amount data for more than one plan or insurance policy or contract (for plans and issuers that enter into a written agreement with another party to provide the information).

D. Enforcement and Good Faith Safe Harbors

The Final Rule will be enforced under the same enforcement framework as under the PHS Act, ERISA, and the Internal Revenue Code for the Affordable Care Act market reform requirements. This means that states have primary enforcement authority over health insurance issuers, HHS has jurisdiction over non-Federal governmental plans and health insurance issuers where HHS determines that a state is not substantially enforcing the requirements, DOL has enforcement authority for group health plans subject to ERISA, and Treasury has jurisdiction over church plans.

The Final Rule includes a few good faith safe harbors to address circumstances in which a plan or issuer, acting in good faith, makes an error or omission in its disclosures, or to account for circumstances in which the plan or issuer's internet website is temporarily inaccessible. In such circumstances, a plan or issuer will not fail to comply with the disclosure requirements if the plan or issuer corrects any error or omission and makes the required information available as soon as practicable.

The Final Rule also provides that, to the extent compliance with the disclosure requirements requires a plan or issuer to obtain information from another entity, the plan or issuer will not fail to comply with the disclosure requirements because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

E. Medical Loss Ratio

The Final Rule allows health insurance issuers that have plans that include provisions encouraging consumers to shop for services from lower-cost, higher-value providers, and the issuer shares the savings with consumers, to take credit for such "shared savings" payments (i.e., actual payments to enrollees) in the numerator of their medical loss ratio ("MLR") calculations.

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