THE WAGNER LAW GROUP

LAW ALERT
Nov. 12, 2020

Agencies Issue Final Regulations Regarding Health Care Transparency

By Barry L. Salkin, Roberta Casper Watson, and Dannae Delano

Last June, in Executive Order 13877, President Trump directed HHS, Treasury, and Labor (collectively, the "Agencies") to solicit comments on how providers, insurers, and group health plans could be required to disclose information about expected out-of-pocket costs before a patient receives care. In response, the Agencies issued proposed regulations earlier this year, and recently issued final regulations. A significant portion of the preamble to the proposed regulations was devoted to the various policy purposes served by the regulations, and responding to various challenges expressed in comments on the proposed regulations; the Agencies did not have the authority under the Affordable Care Act and Public Health Services Act to enact these regulations; constitutional challenges such as a violation of commercial free speech and an impermissible taking; a violation of the Sherman Anti-Trust Act; and a violation of the Administrative Procedure Act. Whether those responses will suffice to ward off legal challenges to the regulations remains to be seen, but both of the relevant portions of the regulations contain severability provisions, in the event that one, but not both, of the relevant sections is held to be invalid or unenforceable.

Pursuant to the final regulations, participants and beneficiaries who are enrolled in a group health plan would be entitled to receive the following cost-sharing information, which must be accurate at the time the request is made:

1. An estimate of the cost-sharing liability for a covered item or service. Cost-sharing liabilities would include deductibles, coinsurance, and copayments, and would exclude premiums, balance billing amounts for out-of-network service providers, and the cost of items or services not covered under the plan. If the requested items and services are recommended preventive services under the ACA, or if the plan or issuer cannot determine whether the request is for a preventive or nonpreventive purpose, the plan or issuer must display the cost-sharing liability that applies for nonpreventive services, unless the plan or issuer allows the participant to designate the requested item or service by using terms such as preventive, nonpreventive, or diagnostic.
2. Accumulated amounts that the participant or beneficiary has paid to date toward any such amounts, including any expense that counts towards a deductible or out-of-pocket limit, such as a copayment or coinsurance, but excluding amounts such as premium payments, out-of-pocket expenses for out-of-network providers, and items or services not covered under the plan. If an individual has elected coverage other than self-only coverage, any accumulated amount disclosed would reflect both the individual's year-to-date amount and the corresponding amount for the group, including the individual's spouse and other dependents. Accumulated amounts subject to disclosure under the regulation also include limits on items or services, such as the limit on the number of chiropractic visits that will be covered. The remaining number of visits can be provided without making a determination as to whether all of those visits might be medically necessary.
3. An in-network rate, which is comprised of two elements: a negotiated rate, reflected as a dollar amount, for an in-network provider(s) for the requested item or service; and an underlying fee schedule rate, also expressed

as a dollar amount, if it is different from the negotiated rate. The negotiated rate uses the amount a group health plan or health insurance issuer has contractually agreed to pay an in-service provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator. The regulations provide that this rate must be disclosed, even if it is not the rate the plan or issuer uses to calculate cost-sharing liability. In general, plans will not be required to disclose discounts, rebates, or price concessions for drugs.

4. The maximum out-of-pocket allowed amount for an item or service provided by an out-of-network provider, or any other rate that provides a more accurate estimate of an amount a group health plan or issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider. However, in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.
5. If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement, the participant or beneficiary must receive a list of the items and services for which cost-sharing information is being disclosed.
6. If applicable, notice must be provided that coverage of a specific item or service is subject to a prerequisite, which is a certain requirement relating to medical management techniques that must be satisfied before a group health plan or health insurance issuer will cover the item or service. Prerequisites include concurrent review, prior authorization, step-therapy, and fail-first protocols, but do not include medical necessity or other medical management techniques.
7. The notice must include five statements written in plain language:
    i. If balance billing is permitted under state law, a statement that the cost-sharing information provided does not account for the possibility of balance billing, and an explanation of what balance billing is;
    ii. A statement that the actual charges for a covered item or service may be different from the estimate of the cost-sharing liability, depending on the actual items or services the participant or beneficiary receives at the point of care;
    iii. A statement that the estimate for the cost-sharing liability for a covered item or service is not a guarantee that the benefits will be provided for that item or service;
    iv. A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's or beneficiary's deductible and out-of-pocket maximum; and
    v. For items and services that are recommended preventive services under the Affordable Care Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or nonpreventive item or service.

    In addition to the five required statements, additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the information does not conflict with any of the above five items. An example of such a statement would be to advise a participant or beneficiary searching for one service (e.g., surgery) of the potential need to search for other services (e.g., anesthesiologists).

    A model notice has been proposed in a separate piece of guidance to meet these requirements.

The final regulations provide two methods by which the cost-sharing information can be provided: either by an Internet-based self-service tool, or in a paper format. If an Internet-based self-service tool is the method requested, the information must be available in plain language, without a subscription or other fee, that provides a real-time response based on information that is accurate at the date of request. Different searching options are available for in-network and out-of-network providers. The tool should allow users to search for cost-sharing information for a specific in-network provider or to search for all providers using a billing code or a descriptive term such as chest x-rays. The Internet-based self-service tool must allow participants to refine and reorder their search results based on the geographic proximity of in-network providers and the amount of the participant's or beneficiary's estimated cost-sharing liability, if the search for cost-sharing information returned multiple results. If a participant requests that the information be provided to him or her in paper format, the information must be mailed no later than two business days after the individual's request is received. In responding to such a request, the group health plan or issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no more than 20 providers per request. If participants or beneficiaries request disclosure other than by paper, such as by phone or by e-mail, plans and issuers may provide the disclosure through other means, provided the participants and beneficiaries agree that disclosure through such means is sufficient to satisfy the request, and the request is fulfilled at least as rapidly as required for the paper method.

To avoid duplication of effort, a plan and a health insurance issuer can enter into a contract under which the health insurance issuer agrees to provide participants and beneficiaries with the requested information. If the health insurance issuer breaches the contract and fails to provide the requested cost-sharing information, the health insurance issuer, rather than the plan, is in violation of the transparency disclosure requirements. A plan or issuer may also enter into an agreement with a third party to provide such information (e.g., pharmacy benefit manager). However, if a group health plan or issuer enters into such an arrangement and the third party fails to provide the information in compliance with the regulations, the plan or issuer has responsibility for the violation.

This portion of the final regulations applies to plan years beginning on or after January 1, 2023, with respect to the 500 items and services to be published on a publicly available Website, and with respect to all other covered items and services, for plan years beginning on or after January 1, 2024.

The regulations also provide for group health plan information to be provided to the public, subject to the caveat that no such disclosure can violate any health privacy law. The information must be provided in three machine-readable files. The first machine-readable file must include rates negotiated for in-service providers; the second must include information related to the historical data showing allowed amounts for out-of-network providers, which data may be aggregated (although there is an exception when compliance with the regulation would require the plan or issuer to report out-of-network allowed mounts in connection with fewer than 20 different claims for payments under a single plan or coverage); and a prescription drug machine-readable file. The machine-readable files must be publicly available and accessible to any person free of charge. The group health plan or health insurance issuer cannot require a user account, password, other credentials, or submission of personally identifiable information in order to access the file. The machine-readable files must be updated monthly, and the plan or issuer must indicate the date on which the files were most recently updated.

In this context as well, there are special rules to avoid duplication of effort. The first rule is the same as the special rule for disclosures to participants and beneficiaries, in which the health plan issuer will be in violation of the transparency disclosure rules if it enters into an agreement with the group health plan to provide the disclosures, but fails to do so. Additionally, either a group health plan or a health insurance issuer can enter into a written agreement with a third party to provide the required disclosure to the public. However, if the third party fails to provide the written disclosure, then the group health plan or health insurance issuer that entered into the agreement will be in violation of the proposed regulations.

Further, the regulations provide three forms of compliance relief under both of its sections. First, a group health plan or issuer will not be in violation of the regulations if, solely because, in good faith and with reasonable diligence, it makes an error or omission in disclosure, provided the plan or issuer corrects the information as soon as practicable. Second, a group health plan or health insurance issuer will not violate the regulations solely because, despite acting in good faith and with reasonable due diligence, its Website is temporarily inaccessible, provided the plan or issuer makes the information available as soon as practicable. Third, to the extent that compliance with the regulation requires a group health plan or health insurance issuer to obtain information from another party, the group health plan or health insurance issuer will not be in violation of the regulations unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

The statutory basis for issuing these regulations is the Affordable Care Act and the Public Health Services Act, so it is not clear if these regulations could be sustained if the Affordable Care Act is ultimately decided by the Supreme Court to be unconstitutional in its entirety (although based on comments made by the Justices during the recent oral argument before the Supreme Court, it does not appear that outcome is likely). In the interim, employers sponsoring group health plans need to consider the possibility that these regulations will take effect. These rules would not apply to grandfathered plans, excepted benefits, short-term limited duration insurance, health care sharing ministries, health reimbursement accounts, flexible spending accounts, or other account-based group health plans.

www.wagnerlawgroup.com

@wagner-law-group
fb.com/WagnerLawGroup

Boston:
99 Summer Street, 13th Floor
Boston, MA 02110
Tel: (617) 357-5200

@wagnerlawgroup
@wagnerlawgroup

Boynton Beach:
1880 N. Congress Avenue, Suite 200
Boynton Beach, FL 33426
Tel: (561) 293-3590

Chicago:
180 N. LaSalle Street, Suite 3200
Chicago, IL 60601
Tel: (847) 990-9034

Lincoln, MA:
55 Old Bedford Road, Suite 303
Lincoln, MA 01773
Tel: (617) 532-8080

New York:
200 Park Avenue, Suite 1700
New York, NY 10166
Tel: (212) 338-5159

San Diego:
8677 Villa La Jolla Drive, Suite 888
San Diego, CA 92037
Tel: (619) 232-8702

San Francisco:
315 Montgomery Street, Suite 900
San Francisco, CA 94104
Tel: (415) 625-0002

St. Louis:
1099 Milwaukee Street, Suite 140
St. Louis, MO 63122
Tel: (314) 236-0065

Tampa:
101 East Kennedy Boulevard, Suite 2140
Tampa, FL 33602
Tel: (813) 603-2959

Washington, D.C.:
800 Connecticut Avenue, N.W., Suite 810
Washington, D.C. 20006
Tel: (202) 969-2800