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Healthcare cost transparency rules and MLR changes finalized

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Final transparency-in-coverage rules require group health plans and insurance issuers in the individual and group markets to disclose extensive price and cost-sharing information beginning in 2022. Issued by the Treasury and Labor departments and the Centers for Medicare & Medicaid Services (CMS), the final rules have some modifications and clarifications to the proposed regulations. The new regulations and an earlier set of final hospital transparency rules come in response to a 2019 executive order on improving transparency in the cost and quality of healthcare services. Both sets of regulations aim to address wide price variations, reduce waste in healthcare systems and help individuals make informed choices about their healthcare spending. As part of this project, CMS has also added a shared-savings provision to the medical loss ratio (MLR) rules. This GRIST discusses the complex transparency-in-coverage and MLR shared-savings rules that group health plan sponsors will need to understand and prepare to bring their plans into compliance.

Overview of new transparency rules

The new rules require most employer-sponsored group health plans and health insurance issuers to disclose price and cost-sharing information up front, giving enrollees estimates of any out-of-pocket expense they will have to pay to meet their plan's cost-sharing requirements. Health plan sponsors and insurance issuers will also have to give patients and other stakeholders access to previously unavailable pricing information, using a standardized format that allows easy cost comparisons.

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The statutory authority for the new rules derives from Section 2715A of the Public Health Service Act (PHSA), which says that group health plans and issuers must comply with Section 1311(e)(3) of the Affordable Care Act (ACA). That provision requires transparency in coverage and imposes reporting and disclosure requirements for qualified health plans on the public exchanges.

Excluded plans and benefits. Excepted benefits and expatriate plans typically aren't subject to certain PHSA healthcare reform mandates, such as PHSA Section 2715A, so the new rules won't apply, for example, to limited-scope vision or dental plans, retiree-only plans, employee assistance programs that don't provide significant medical care, and certain fixed indemnity policies. The rules specifically provide that the transparency requirements also won't apply to grandfathered plans, health reimbursement arrangements (HRAs) and other account-based plans (apparently regardless of excepted-benefit status), or short-term limited-duration insurance (STLDI).

No quality metrics for now. The proposed regulations requested comments about using provider quality measurements and reporting in the private healthcare market to complement cost-sharing transparency. While regulators received a number of comments supporting this idea, the final rules do not require any quality metrics. The agencies intend to consider the comments for future action and encourage plans to innovate with quality metrics to improve consumers' healthcare decisions.

Key transparency disclosures. Most plans will have to make cost information available in two ways:

- Posting machine-readable files with pricing information on a publicly accessible internet site
- Providing a self-service tool for enrollees to obtain personalized out-of-pocket cost estimates

Machine-readable pricing files on the internet for public access

To facilitate price comparisons and consumerism in the healthcare market, health plans and insurance issuers will need to make three machine-readable files publicly available on the internet:

- In-network rate file
- Allowed amount file
- Prescription drug file

These regularly updated, standardized files will contain, among other things, the plan's in-network provider negotiated rates, historical payments of allowed amounts paid to out-of-network providers and prescription drug rates. The files must provide information for all covered items and services, including prescription drugs. As discussed later, each file must contain certain content elements.

Effective date. The files must be available for plan years beginning on or after Jan. 1, 2022.

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Self-service cost-estimator tool for enrollees

Plans and issuers will need to provide an internet tool that enables enrollees to obtain personalized out-of-pocket cost estimates for in- and out-of-network healthcare items and services, including durable medical equipment and prescription drugs. Plans and issuers can limit the tool's availability to enrollees and have no obligation to give access to employees or dependents who might become covered in the future. When making healthcare decisions, enrollees may choose to share their personal cost-sharing liability with a healthcare provider or authorize a provider to serve as their representative under ERISA's claim procedure rules.

This tool will help enrollees understand how their plan determines cost-sharing amounts and facilitate comparison-shopping before receiving medical care. As discussed later, the tool must include certain content elements — generally, the same information found in a healthcare claim's explanation of benefits (EOB). The rules don't require outreach or education, but regulators encourage plans to promote awareness of the self-service tool and ways enrollees can use it to shop for lower-priced services.

Effective date. The self-service transparency tool will phase in over two years:

- ***Plan years beginning on or after Jan. 1, 2023.*** Plans and issuers must provide estimates for 500 items and services identified in Table 1 of the preamble to the final rules. Regulators have provided the required plain-language descriptions (e.g., stress test with echocardiogram) for these items and services, along with standard billing codes.
- ***Plan years beginning on or after Jan. 1, 2024.*** Plans and issuers must disclose estimates for all covered items and services.

Required disclosure methods and formats

The rules specify a number of required methods and formats for providing the self-service transparency tool and the machine-readable files.

Machine-readable files

Regulators will develop technical implementation guidelines and schemas for creating the machine-readable files. The agencies intend to make these guidelines available on GitHub, a development platform. The files must be publicly available without any charge or access conditions (like user accounts, passwords or other credentials, or submission of personally identifiable information). The files must be updated monthly and indicate the date of the most recent update.

The allowed out-of-network amount file may be hosted on a third-party website, but the plan's website would need to provide a link to the other site. The rules do not say whether a third-party website could also host the other machine-readable files (the in-network rate and prescription drug files).

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Self-service tool

This self-service internet tool must provide plain-language information on an enrollee's cost-sharing expenses for healthcare items and services. The tool must give real-time cost-sharing information that is accurate at the time of the request. The tool must be free of charge and allow users to:

- Search for cost-sharing information for a covered item or service by a specific in-network provider or all in-network providers by inputting:
  - Billing codes (e.g., CTP code 87804) or descriptive terms ("rapid flu test")
  - Name of the in-network provider, if applicable
  - Other factors used by the plan (such as location, facility name or dosage)
- Search for an out-of-network allowed amount, percentage of billed charges or other rate that provides a reasonably accurate estimate of the amount the plan will pay for a covered item or service by inputting:
  - Billing codes or descriptive terms
  - Other relevant factors (e.g. location where the item or service will be provided)
- Refine and reorder search results based on the geographic proximity of in-network providers and the amount of the enrollee's estimated cost-sharing liability for the covered item or service

Plans must also provide this information, without charge, on paper (or another means like email or telephone) within two business days of receiving a request from a participant or beneficiary. Plans supplying paper disclosures can choose to cap the number of cost-sharing estimates provided, but any limit must allow estimates for at least 20 providers per request.

Required content elements

Required content elements for the self-service transparency tool and the machine-readable files have some similarities, but some key elements differ for the machine-readable files. The chart below briefly lays out the content elements and their applicability to each type of transparency disclosure. The sections following the chart describe these content elements in more detail.

Content element	Machine-readable files	Self-service tool
Cost-sharing liability	Not required	Required
Accumulated amounts	Not required	Required
In-network rate (negotiated rate and fee schedule)	Required	Required

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Content element	Machine-readable files	Self-service tool
Out-of-network allowed amount	Required	Required
Historical net prices for prescription drugs	Required	Not required
Items and services subject to bundled payment	Required	Required
Notices	Not required	Required

Calculating cost-sharing liability (self-service tool only)

The self-service tool — but not the machine-readable files — must give an estimate of an enrollee's cost-sharing liability for a covered item or service (including under a bundled-payment arrangement) at a particular provider or multiple providers. The estimate must incorporate an enrollee's accumulated cost-sharing amounts, the in-network rate (including the negotiated rate and the underlying fee-schedule rate if it differs from the negotiated rate), and out-of-network allowed amounts. Plans and issuers may choose to add other metrics (like quality metrics) and analytics beyond this minimum standard. Regulators will assess the value of requiring additional information going forward.

The tool must provide cost-sharing information in plain language. The information must be written and presented in a manner calculated to be readily understood, taking into account the average enrollee's level of comprehension and education, as well as the complexity of plan terms.

The cost-sharing estimate must be "accurate at the time the request is made." The estimate does not have to provide the actual or final cost of a particular item or service or factor in any unanticipated costs due to the severity of illness, provider treatment decisions or other unforeseen events. Nor does the estimate need to account for outstanding claims that haven't been processed.

A special rule applies to cost-sharing estimates for preventive care, since plans may not know in advance whether a particular item or service will be classified as preventive care (free of cost sharing) or nonpreventive (subject to cost sharing). If the plan can't make that determination, the tool must display the nonpreventive cost-sharing liability, along with a statement that cost sharing will not apply if the item or service is billed as an in-network preventive service. Alternatively, a plan may allow the enrollee to specify whether the requested cost-sharing estimate is for preventive or other care.

Accumulated amounts (self-service tool only)

The self-service tool — but not the machine-readable files — must include the enrollee's accumulated amounts, defined as the enrollee's incurred financial responsibility at the time of the estimate. The accumulated amount must include all forms of cost sharing, including deductibles, coinsurance and copayments, but not premiums, balance-billing amounts charged by out-of-network providers, or the cost

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of noncovered items or services. The accumulated amount must include information related to the individual and family (or other than single coverage) deductible and/or out-of-pocket limit.

The accumulated amount must also include the enrollee's accruals toward any cumulative treatment limit on a particular item or service (such as a limit on items, days, units, visits or hours in a defined period), without regard to any medical-necessity determinations.

> *Example.* A plan covers 10 physical therapy visits in a plan year, subject to a medical-necessity determination. At the time of the enrollee's request for a cost-sharing estimate, the plan has paid claims for three visits with the physical therapist. The tool's accumulated amount must reflect that the plan has paid for three of 10 visits, regardless of whether a medical-necessity determination has been made for the future seven visits.

The accumulated amount doesn't need to reflect any separate account-based arrangement (like an HRA), but regulators encourage plans to issue a disclaimer about those arrangements.

In-network rates, including negotiated rates (self-service tool and machine-readable files)

Plans and issuers must disclose negotiated rates through the self-service tool and in two of the machine-readable files (the in-network rate and prescription drug files). The negotiated rate is the amount that a plan or an issuer has contractually agreed to pay — whether directly or indirectly through a third-party administrator (TPA) or a pharmacy benefit manager (PBM) — to an in-network provider, including a pharmacy or other prescription drug dispenser, for covered items and services.

Machine-readable files (in-network rate and prescription drug files). The rules have specific parameters for providing negotiated rates to the public through the machine-readable files. The in-network and the prescription drug files must include for each coverage option:

- ***Name and identifier*:** the Health Insurance Oversight System (HIOS) identifier or the employer identification number (EIN) if the HIOS identifier is not available
- ***Billing code:*** the billing code (the National Drug Code (NDC) for prescription drugs) and a plain-language description of each covered item or service
- ***Applicable rates:*** dollar amounts for all applicable rates, including negotiated rates, underlying fee-schedule or derived amounts, or if rates can be adjusted for a particular enrollee, the base rate
  - If a plan doesn't use negotiated rates for provider reimbursements, it should disclose derived amounts, if calculated in the normal course of business (e.g., for capitated arrangements). A derived amount is the price a plan assigns to an item or service for internal accounting, reconciliation with providers or data submissions.

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  - If a plan uses underlying fee-schedule rates to calculate cost sharing, the files must provide those rates in addition to the negotiated or derived rates.
  - The prescription drug file must include both the negotiated rate and the "historical net price" for covered drugs, inclusive of rebates, chargebacks, fees and any additional price concessions (see the discussion below on special issues related to prescription drugs).
- Rates must be:
  - Associated with the national provider identifier (NPI), taxpayer identification number (TIN) and place-of-service code for each in-network provider
  - Associated with the last date of the contract term for the rate
  - Notated when a reimbursement arrangement other than fee-for-service applies (such as a capitation or bundled-payment arrangement)

Self-service tool. The tool must disclose negotiated rates as a dollar amount, even though some provider contracts express negotiated rates as a formula (e.g., 150% of the Medicare rate). Plans must disclose any underlying fee schedule used to determine cost-sharing liability only if that schedule differs from the negotiated rate. The tool must give the negotiated rates, even if they are not used to calculate cost-sharing liability (e.g., when the copayment is a flat-dollar amount or the enrollee has met the deductible). Regulators recognize that enrollees may not owe any cost sharing for a particular item or service (e.g., a prescription drug), but the tool still must provide the negotiated rate.

Out-of-network allowed amounts (self-service tool and machine-readable file)

Plans and issuers must disclose out-of-network allowed amounts through the self-service transparency tool and in the machine-readable allowed amount file. The out-of-network allowed amount is the maximum a plan will pay for a covered item or service furnished by an out-of-network provider. The requirements for this disclosure differ somewhat for the self-service tool and the machine-readable file.

Machine-readable file. This file must include unique out-of-network allowed amounts and billed charges for covered items and services furnished during the 90-day period that began 180 days prior to the file's publication date. A plan must exclude data involving fewer than 20 different claims for a particular item or service. The rules don't require disclosing any information that would violate applicable privacy laws. A plan may use aggregate data (collected from multiple plans or issuers) under certain circumstances.

Each unique out-of-network allowed amount must be:

- Reflected as a dollar amount
- Associated with the NPI, TIN and place-of-service code for each out-of-network provider

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Example. An out-of-network provider submits 25 claims to a plan for an item. The 25 claims have three different billed charges ($100, $150 and $200) and two different allowed amounts ($50 and $150). The plan should have one entry for each of the six unique combinations of billed charges and allowed amounts submitted by the provider:

- Entry A has a billed charge of $100 and an allowed amount of $50.
- Entry B has a billed charge of $150 and an allowed amount of $50.
- Entry C has a billed charge of $200 and an allowed amount of $50.
- Entry D has a billed charge of $100 and an allowed amount of $150.
- Entry E has a billed charge of $150 and an allowed amount of $150.
- Entry F has a billed charge of $200 and an allowed amount of $150.

Self-service tool. Plans must disclose the out-of-network allowed amount or any other rate — such as the usual, customary and reasonable (UCR) rate — that provides a more accurate estimate of what the plan will pay for the requested item or service. The tool generally should disclose the allowed amount in dollars. However, if the plan reimburses an out-of-network provider as a percentage of the billed charge for a covered item or service, then the tool can give just the percentage.

Bundled rates (self-service tool and machine-readable files)

In-network rates disclosed in the machine-readable files and through the self-service transparency tool must include any items or services covered by a bundled-payment arrangement (e.g., for diagnostic imaging). This type of arrangement pays a provider a single payment for all covered items and services provided to a patient for a specific treatment or procedure.

The self-service tool must disclose a list of the covered items or services subject to a bundled-payment arrangement, along with the individual’s cost-sharing liability under the arrangement. The plan doesn’t have to disclose a separate cost-sharing estimate for each item or service under the bundled arrangement, unless a particular item or service has a separate cost-sharing liability.

Example. A provider is reimbursed for a surgical procedure that includes the surgery and pre- and post-surgery office visits, while the enrollee is billed a copayment for each office visit and a coinsurance amount for the surgery. Under this arrangement, the cost-sharing tool should provide estimates of the enrollee’s separate copays and the coinsurance amount. If the bundled arrangement instead had one copayment for all office visits and the surgery, then the tool should provide an estimate of the enrollee’s bundled copayment.

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These requirements apply to other alternative payment models as well, such as referenced-based pricing, direct primary care, capitated arrangements and value-based arrangements.

Notices (self-service tool only)

Plans must provide certain notices through the self-service transparency tool, including the following information:

- An item or service is subject to a prerequisite. Prerequisites mean requirements for concurrent review, prior authorization, and step-therapy or fail-first protocols before the plan will cover certain items or services. Prerequisites don't generally include medical-necessity determinations or other medical-management techniques.
- Out-of-network providers may bill patients for any charges exceeding the allowed amount, and the cost-sharing estimate doesn't reflect this balance billing.
- Actual charges may differ from the cost-sharing estimate, depending on the items or services received at the point of care.
- The estimate is not a guarantee that benefits will be provided for that item or service.
- The plan does (or does not) count copayment assistance and other third-party payments toward the deductible and out-of-pocket maximum.
- Cost sharing may not apply to in-network preventive-care items or services (if the request doesn't indicate whether the item or service is preventive care).

A plan may include additional information, including disclaimers, as long as they don't conflict with the required notices.

Special issues related to prescription drug requirements

Regulators acknowledge that disclosing prescription drug information will create unique challenges for plans, given the complexity of drug pricing. Drug prices are often determined using a formula applied at the point of sale and can change daily. Nevertheless, regulators decided that the complexity of drug pricing is not a reason to exclude this information from the machine-readable file and cost-sharing tool.

Both the self-service tool and the machine-readable file must include negotiated rates for prescription drugs, along with other information. The negotiated rate is defined broadly to recognize that the benchmark or formula used to determine the negotiated price — whether the wholesale acquisition cost (WAC), average wholesale price (AWP), maximum allowable cost (MAC) or UCR — may differ by drug or drug class in a contract.

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Self-service tool. The self-service tool must disclose the plan's negotiated rate used to reimburse providers on "the date the file is extracted." This rate generally doesn't include any rebates, discounts and other price concessions applied after the point of sale, so the cost-sharing estimate won't reflect this information.

Machine-readable file. In contrast, the prescription drug file must include not only the negotiated rate but also each covered prescription drug's historical net price. As stated earlier, the net price is the price after post–point-of-sale discounts are deducted. The historical net price is the retrospective average amount a plan has paid to an in-network provider (such as a pharmacy or other drug dispenser), including the dollar value of "reasonably allocated" rebates, discounts, chargebacks, fees and other price concessions. The historical average must be calculated over a 90-day period beginning 180 days before the publication date of each prescription drug file.

Contracting with issuers, TPAs, PBMs and other vendors

Employers previously have not had to provide extensive cost-sharing and pricing disclosures to participants, although some transparency tools for group health plans have emerged in recent years. As a result, most employers currently don't have access to the extensive data necessary to provide the disclosures. Many employers may have to revise their vendor contracts or engage a new vendor to collect and present the data required for the machine-readable files and the self-service tool.

The rules allow a self-funded plan to satisfy the disclosure requirements by entering into a written agreement with another party (like a TPA or a healthcare claims clearinghouse) to provide the necessary information. However, if the other party fails to provide information in compliance with the rules, the plan will be responsible for the violation, unless one of the good-faith protections applies (described in the next section). In contrast, if an insured plan has a written agreement requiring the insurance carrier to provide the transparency information, then the carrier will be responsible for any compliance failure.

Enforcement

The Labor Department will enforce the transparency rules for ERISA-covered group health plans, while Treasury will enforce the rules for certain church plans. As with other ACA rules that have a triagency enforcement framework, DOL can refer any violations to IRS, which can assess daily penalties of $100 per participant for noncompliance. CMS has jurisdiction over state and local government plans, as well as health insurance issuers in states that fail to substantially enforce the rules.

Good-faith protections. Plans will not fail to comply or face enforcement action under any of these conditions:

- The plan made an error or omission in a disclosure while acting in good faith and with reasonable diligence, provided the information is corrected as soon as practicable.

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- The website hosting the self-service tool or machine-readable files is inaccessible, provided the plan makes the information available as soon as practicable.
- Information supplied by another entity to the plan is incomplete or inaccurate, as long as the plan relied in good faith on that entity and did not know or should have known that the information was incomplete or inaccurate.

As noted earlier, a special rule places the burden of compliance on the insurance carrier rather than the insured plan if the carrier has agreed in writing to provide transparency information.

Potential litigation

Many comments on the proposed regulations raised a wide variety of legal issues, including constitutional concerns about compelled commercial speech and potential violations of state and federal laws that protect proprietary, confidential business information and trade secrets. Certain stakeholders are likely to sue to enjoin and overturn the transparency-in-coverage rules, and litigation challenging the hospital transparency rules is already underway. The agencies added severability clauses to the final transparency-in-coverage rules so if a reviewing court finds one provision unlawful, the remaining rules should take effect.

Hospital transparency final rules

The hospital transparency final rules require hospitals to make public their standard charges for items and services delivered. Hospitals must publish five types of standard charges in a “consumer-friendly disclosure” and in machine-readable files:

- The gross charges for an individual item or service that is reflected on a hospital’s chargemaster (absent any discounts)
- The discounted cash price (the charge to an individual who pays cash or a cash equivalent) for a hospital item or service
- The payer-specific charge that a hospital has negotiated with a third-party payer for an item or service
- The deidentified minimum negotiated charge (the lowest charge that the hospital has negotiated with all third-party payers for an item or service)
- The deidentified maximum negotiated charge (the highest charge that a hospital has negotiated with all third-party payers for an item or service)

The consumer-friendly disclosure can be met using a price estimator tool and only has to include data for 300 shoppable services. Of those shoppable services, CMS selects 70 and a hospital selects the

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remaining 230. The machine-readable files must include data about all items and services provided by the hospital.

Effective date. The hospital transparency rules take effect beginning Jan. 1, 2021, but have been challenged in court (*Am. Hosp. Ass'n v. Azar*, 2020 WL 3429774 (D.D.C. June 23, 2020)). A federal district court declined to overturn those rules, but that ruling has been appealed.

MLR shared savings

Beginning with the 2020 MLR reporting year, issuers may reduce MLR rebates by including in the MLR calculation's numerator — the issuer's incurred claims plus quality-improvement expenditures — any "shared savings" payments made to an enrollee for choosing a lower-cost, higher-value healthcare provider. This rule may encourage issuers to incentivize enrollees to shop for less expensive providers and to share those savings with enrollees. The shared savings could be, for example, a flat-dollar amount based on a schedule that tiers providers by rates charged. The shared savings could take a number of forms, such as a gift card, a cost-sharing reduction or a premium credit.

Next steps for employers

To comply with these rules, most employers will need to work closely with insurers, TPAs and point-solutions (like fertility point solutions) vendors that have the needed pricing data. Employers and other stakeholders may get an idea of the transparency information's value in promoting cost-conscious healthcare decisions once the hospital data becomes public (perhaps as soon as 2021). Employers sponsoring health plans should begin preparing to comply with the transparency-in-coverage rules by taking these steps:

- Review and survey employees to get feedback on any current transparency tool and its utility.
- Review hospital transparency data when this information becomes available.
- Consider where to post the machine-readable files and the self-service transparency tool.
- Note the technical differences in the data elements required for the machine-readable files vs. the self-service tool. Assemble open questions about implementation. Look out for the agencies to issue technical implementation guides in the future.
- Determine the ability and willingness of insurers, TPAs, PBMs and point-solutions vendors that have pricing data to provide the required information. Review and update contracts as necessary for the transparency obligations.
- Consider whether and how to incorporate quality metrics, although the transparency rules do not currently require including these metrics.

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- Project impacts on plan costs and current cost-projection calculations. Employers may want to consider how utilization may shift when pricing comes to light. If enrollees use the new tool, employers may see cost savings and should review the impact on plan costs.

- Plan to develop communications for enrollees and responses to increased inquiries. Participants need to understand that the self-service tool gives only estimates of cost-sharing liabilities, and actual charges may differ depending on the actual services delivered, provider decisions and unforeseen circumstances that arise in the course of treatment.

- Evaluate any potential privacy or cybersecurity risks with the self-service tool and machine-readable files.

- Stay informed about litigation challenging the rules and any regulatory changes that the new administration might make.

- Consider how the new MLR rules will affect insured plans.

- Identify opportunities to use the newly available data to educate participants and drive value-based healthcare decisions.

Related resources

Non-Mercer resources

- Final transparency rules for group health plans and insurance issuers (Federal Register, Nov. 12, 2020)

- Fact sheet on final transparency rules for group health plans and insurance issuers (CMS, Oct. 29, 2020)

- News release on final transparency rules for group health plans and insurance issuers (CMS, Oct. 29, 2020)

- Transparency-in-coverage resources (DOL)

- *Am. Hosp. Ass'n v. Azar*, 2020 WL 3429774 (D.D.C. June 23, 2020); *appeal filed*, Docket No. 20-5193 (DC Cir. July 17, 2020)

- Proposed transparency rules for group health plans and insurance issuers (Federal Register, Nov. 27, 2019)

- Final transparency rules for hospitals (Federal Register, Nov. 27, 2019)

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Mercer Law & Policy resources

- Top 10 compliance issues for health and leave benefits in 2021 (July, 20, 2020)
- Healthcare law and policy outlook for 2020 (Feb. 18, 2020)
- Mercer comments on proposed transparency in coverage rules (Jan. 31, 2020)
- Executive order targets healthcare price and quality transparency, and HSA/FSA changes (July 10, 2019)
- Top 10 compliance issues for 2020 health and fringe benefit planning (June 25, 2019)
- Mercer shares views with senators on controlling healthcare costs (March 6, 2019)

Other Mercer resources

- Transparency rules: 5 considerations for employers (Nov. 12, 2020)
- New transparency rule requires plan sponsors to disclose costs up front (Oct. 29, 2020)
- Executive order on transparency, HSAs: What employers need to know (June 27, 2019)
- The new transparency regulations: Will consumers finally be able to shop for healthcare? (Nov. 21, 2019)

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