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EXECUTIVE ORDER TARGETS HEALTHCARE PRICE AND QUALITY TRANSPARENCY, AND HSA/FSA CHANGES

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An executive order signed by President Trump on June 24 directs certain federal agencies to issue regulations and take other actions to improve transparency in the cost and quality of common healthcare services. The order also directs the Treasury Department to issue guidance expanding the use of health savings accounts (HSAs) by people with chronic conditions and increasing the flexible spending arrangement (FSA) funds that can carry over to the next year without penalty. While the order doesn't trigger immediate regulatory or other legal changes, it does signal the administration's next areas of focus for healthcare regulation.

MOST DIRECTIVES COULD AFFECT EMPLOYER-SPONSORED PLANS

The order directs specific agencies to issue proposed rules, requests for information and reports aimed at ensuring patients have better information about the actual prices, out-of-pocket costs and quality of typical medical treatments and services. Any final regulations could affect not only providers and insurers, but also self-insured group health plans. The order requires the following agency actions:

- ***By Aug. 23, a proposed regulation requiring that hospitals post standard charge information.*** The order directs the secretary of Health and Human Services (HHS) to issue proposed regulations requiring hospitals to publicly post standard charge information for common or "shoppable" items. The posted information must be "based on negotiated rates," provided in a user-friendly format, and updated regularly.

- ***By Sept. 22, an advance proposed rule on patient access to out-of-pocket costs.*** The order requires the secretaries of HHS, Treasury and the Department of Labor (DOL) to issue an advance notice of proposed rulemaking (ANPRM) seeking comments on ways to require self-insured group health plans, insurers and providers to facilitate or provide access to the "expected" out-of-pocket costs of a treatment or service before the care is provided. ANPRM's are sometimes used by agencies to gather information and ideas about planned guidance before it is officially proposed.

- ***IRS guidance on certain account-based plans.*** In addition to cost transparency directives, the order tasks the IRS with providing guidance intended to give patients more control over their "healthcare resources":
  - ***HDHP/HSA guidance by Oct. 22.*** IRS must issue guidance to expand the ability of individuals to select high-deductible health plans alongside HSAs (HDHP/HSA) and allow such plans to cover low-cost preventive care before the deductible to help "maintain health status for individuals with chronic conditions." The language in the order is broad but appears to support changes employers have been advocating for some time — namely, more specifics on what items, services and medications can be provided to patients with chronic illness before they reach the deductible without interfering with HSA eligibility.
  - ***FSA carryover guidance by Dec. 21.*** The IRS must also issue guidance aimed at increasing the amount of FSA funds that individuals can carry over at the end of the year without penalty.
  - ***Proposed regulations by Dec. 21 that could potentially make expenses for direct primary care arrangements and health sharing ministries eligible medical expenses under the tax code.*** The proposed rules would presumably allow account-based plans to pay for these alternative arrangements — and possibly others. Under a direct primary care arrangement, a patient or plan typically contracts directly with a primary care provider to deliver primary care services for a set monthly fee. Health sharing ministries, which were referenced in Affordable Care Act (ACA) regulations that provided exceptions to the individual mandate, allow individuals with common religious beliefs to pool payments to cover member medical expenses.
- ***By Dec. 21, increase access to deidentified claims data.*** HHS is directed to increase access to deidentified claims data from "taxpayer-funded healthcare programs and group health plans." HHS — in consultation with Treasury; DOL; the departments of Defense (DoD) and Veterans Affairs (VA); and the Office of Personnel Management — must increase access to this data so researchers, innovators and others may use it to develop tools that allow patients to be better informed about their healthcare options. The order appears to require HHS to look to existing datasets to deidentify this information and make it available to researchers.
- ***By Dec. 21, issue various reports to inform transparency initiatives.*** Federal agencies are also tasked with issuing reports related to price and quality transparency:
  - ***Impediments to transparency.*** HHS, in consultation with the US attorney general and the Federal Trade Commission, must issue a report that describes how the federal government and the private sector "[impede] healthcare price and quality transparency for patients" and recommends strategies for eliminating these barriers and increasing competition. The report must include information on why lower-cost providers avoid healthcare advertising.
  - ***Surprise medical billing.*** HHS must report on additional steps needed to implement principles that the administration released on May 9, 2019, to address surprise medical billing.

- ***Quality measures alignment.*** HHS, the DoD and the VA must issue a "Health Quality Roadmap" that outlines a strategy to align and improve reporting on data and quality measures in Medicare, Medicaid, the Children's Health Insurance Program, the Health Insurance Marketplace (public exchanges), the Military Health System and the Veterans Health Administration. HHS recently announced a Quality Summit to be scheduled to begin development of the roadmap.

POTENTIAL FOR CHANGE?

While the directives could hold some promise for added healthcare cost and quality transparency, similar objectives have been the topic of regulatory and congressional action in the past, with limited results. Still, the pressure to find workable solutions to rising healthcare costs continues to build, especially among employers, who are the primary purchasers of health coverage.

A recent study by the RAND Corp. found that relative prices paid by private health plans for hospital charges were 241% of what Medicare pays, with wide variations from state to state. The study suggests that employers could reduce costs by shifting patients to lower-priced providers, but "effective steering requires a detailed awareness of the prices paid to each provider coupled with information about types of services offered and the quality of care provided." As more employers seek access to this information, they will want to pay attention to what the agencies issue in the coming months under this transparency order.

Existing Authority

The agencies will need to look to their authority under existing laws to make the ordered changes. And regulators are likely to be mindful of recently successful challenges to regulations issued in response to the Trump administration initiatives. Earlier this year, a federal court struck down portions of the final Trump administration rule on association health plans as beyond the scope of the government's authority (*New York v. Dep't of Labor*, No. 18-1747 (D.D.C. March 28, 2019)). And drug manufacturers successfully challenged final HHS rules requiring list prices of medications to be included in television advertisements. The drug companies alleged that HHS lacked the statutory authority to require the disclosure, which the plaintiffs claimed also violated their First Amendment rights. In a recent ruling, a federal trial court vacated the regulation, finding that HHS exceeded its authority (*Merck & Co., Inc. v. Dep't of Health & Human Servs.*, No. 19-cv-01738 (D.D.C July 8, 2019)).

Agencies will likely rely on existing authority, including the following, to require reporting and disclosure and impose other transparency mechanisms:

- ***The ACA.*** In the years leading up to the passage of the ACA, Congress examined mechanisms to provide individuals with more information about their health coverage. Some of the transparency initiatives included in the law:
  - Require each hospital to publicly disclose a "list of the hospital's standard charges" (ACA Section 2718(e)). While recent Medicare rules have updated the implementation of this requirement, some critics claim that the information provided by hospitals isn't useful for consumers as it only includes list prices, not information about actual negotiated prices or out-of-pocket costs. The order appears to address this by requiring hospitals to include information "based on negotiated rates," for "common" or "shoppable" items.

  - Require plans to provide patients with a uniform explanation of coverage that includes a "coverage facts label" listing common benefits and "related cost sharing" (ACA Section 2715). The resulting Uniform Summary of Benefits and Coverage (SBC) incorporates a coverage fact label for a handful of items, but the prices listed are only estimates.

  - Require disclosure by plans and issuers of certain data about claims and coverage as well as reporting of specific quality information (ACA Sections 2715A & 2717). These items, effective in 2014, were not implemented for employer-sponsored plans. The DOL included some of this data collection and sought input on quality and other reporting in a proposed Form 5500 rule update issued in 2016. The rule has not been finalized.

- ***ERISA.*** Regulators will likely explore existing rules under ERISA as they develop regulations that would apply to the private sector. In addition to the ACA rules mentioned above that apply to plans (and are incorporated into ERISA by the ACA), other existing rules address:

  - ***Reporting and disclosure (29 U.S.C § 1021).*** Regulators will need to assess whether they have authority under these ERISA provisions to provide increased information on an employee's out-of-pocket costs and increase access to deidentified claims data for researchers and innovators. Though not mentioned in the transparency order, a federal all-payer claims database is already under discussion. No federal agency currently collects claims data from ERISA-sponsored self-insured plans. In 2015 a US Supreme Court decision in *Gobeille v. Liberty Mutual Ins. Co.* found that ERISA preempted Vermont's all payer claims reporting mandate so that it did not apply to self-insured ERISA plans. In the decision, the court noted that DOL, "may be authorized to require ERISA plans to report data similar to that which Vermont seeks."

  - ***Fiduciary duties (29 U.S.C § 1101).*** Under ERISA, plans must serve exclusively to provide benefits for participants and beneficiaries, and fiduciaries must defray reasonable expenses for administering the plan. Whether these provisions mean plan fiduciaries must provide cost and quality information to participants and beneficiaries is a key question. A 1998 DOL information letter suggests that plan fiduciaries should identify, collect and evaluate quality information when choosing healthcare service providers, and look at such factors as the cost and the quality of the service provider and have knowledge of the prevailing rates for similar services. This, however, has not been the topic of formal agency regulations.

- ***Internal Revenue Code.*** The order's three Treasury items target HSA and FSA rules, along with a specific directive to broaden what is treated as a qualified medical expense under the tax code:

  - ***Predeductible HDHP/HSA coverage for the chronically ill.*** The order contains broad language for initiatives to expand access to HDHP/HSAs but also specifically addresses providing the arrangement to patients with chronic illnesses so they can access preventive care that "helps maintain" their health status before meeting the deductible. The law that created HSAs requires that the accompanying HDHP not provide benefits until the minimum deductible for that year is satisfied. The law includes an exception that allows predeductible reimbursement of preventive care. The law doesn't define "preventive care." but the term is described as being "within the

meaning of Section 1871 of Social Security Act, except as otherwise provided by the Secretary." While the IRS must look to the meaning of the term in the Social Security Act, the agency appears to have the authority to interpret the term on its own. Early HSA guidance indicated that benefits meant to treat "an existing illness, injury or condition" are not preventive. In recent years, there have been calls to update the guidance on preventive care to include services and medications that prevent chronic disease progression (for instance, insulin for a diabetic). New guidance under the order is expected to move in this direction. Regulators will likely have to assess whether any new predeductible coverage will increase costs to plan sponsors and Treasury.

- ***FSA carryovers.*** The order directs Treasury to issue guidance to increase the amount that individuals with a health FSA can carry over to the next year. In general, cafeteria plans can't include any plan that provides for deferred compensation (IRC Section 125(d)(2)(A)). As a result, longstanding proposed cafeteria plan rules include a use-it-or-lose-it feature that prohibits unused benefits or contributions from carrying over to the following plan year. In 2013, the IRS issued a notice modifying that rule and allowing health FSAs that meet certain requirements to carry over up to $500 to the next plan year. The order could prompt the IRS to increase the $500 carryover amount or expand the 2013 rule beyond health FSAs.

- ***Eligible medical expense.*** Section 213(d) of the tax code defines what items are considered medical expenses that can be reimbursed not only for account-based arrangements but all employer-sponsored health coverage subject to preferential tax treatment. Section 213(d) also describes which medical expenses are eligible for the individual tax deduction for medical expenses. The order directing Treasury to include direct primary care arrangements and healthcare sharing ministries as Section 213(d) medical expenses might allow individuals to get a medical expense deduction for these arrangements and use them as their sole source of health coverage. But to the extent these arrangements are paired with a HDHP/HSA, paying for them predeductible is still prohibited, unless they meet the preventive care or another exception.

Opposition and Pending Legislation

The executive order is already generating controversy, with opposition groups, including some hospital and insurer groups, raising concerns about the release of negotiated prices, saying the information is proprietary and disclosure could raise, not reduce, prices. Critics also point to the confidential nature of the information and warn disclosure could lead to claims of antitrust violations. Given this, any final rules are may face legal challenges in the courts.

Meanwhile, a Senate committee recently passed bipartisan legislation that, while aimed at ending surprise billing, also includes transparency provisions. The draft legislation would require providers, plans and insurers to disclose cost-sharing estimates to patients before receipt of care and require pharmacy benefit managers to disclose certain information to plan sponsors and pass though all rebates to the plan. The legislation would also require the DOL to contract with a nonprofit entity to create a claims database. If the legislation is enacted with these provisions, it would give the agencies specific authority to act in some areas covered by the order.

Employer Input

Plan sponsors should consider responding to agency requests for information and submitting comments on proposed regulations. Any agency working on transparency initiatives will have to weigh the additional burdens of increased reporting and disclosure against the needs of individuals to make informed and cost-effective decisions about medical care. When drafting responses to anticipated agency actions, employers should consider the following:

- Some policymakers are hoping that broader access to this information by plan fiduciaries as well as individual employees will lower prices due to added choice and competition. This view is supported by the RAND study's findings.

- Technology developments in the nearly 10 years since passage of the ACA hold some promise for making data collection, analytics and disclosure much easier and perhaps less expensive. More vendors are offering transparency tools that aim to provide information to individuals about cost and quality before care is provided. But employer-sponsored plans might not have access to the data that their third-party administrators and other vendors do, which may present challenges if the plans must make these disclosures.

- Agencies will need information about the operational barriers that may exist to providing cost and quality information — from medical coding and retrospective billing to data privacy and security — and ways to address these challenges as well as promote employee engagement in seeking this information.

- Aside from the transparency initiatives, efforts to reform HSA rules to address reimbursement of specific items and services before the deductible could result in useful clarification of existing guidance. Employers should look for some changes in this area, as HSA's are broadly supported by the Trump administration.

RELATED RESOURCES

Non-Mercer Resources

- Decision in *Merck & Co., Inc. v. Dep't of Health & Human Servs.*, No. 19-cv-01738 (D.D.C. July 8, 2019)
- Decision in *New York v. Dep't of Labor*, No. 18-1747 (D.D.C. March 28, 2019).
- Prices Paid to Hospitals by Private Health Plans Are High Relative to Medicare and Vary Widely: Findings From an Employer-Led Transparency Initiative (RAND Corp., July 8, 2019)
- Executive Order 13877: Improving Price and Quality Transparency in American Healthcare to Put Patients First (Federal Register, June 27, 2019)
- Fact Sheet (White House, June 24, 2019)
- Final Rule: Medicare FY 2019 Hospital Inpatient Prospective Payment Systems (Federal Register, Aug. 17, 2018) (see hospital charge discussion at pp. 41686-41687)

- Additional FAQs on Requirements for Hospitals To Make Public a List of Standard Charges via Internet (CMS, Dec. 3, 2018)
- FAQs on Requirement for Hospitals To Make Public a List of Standard Charges via Internet (CMS, Sept. 27, 2018)
- Examining a Heathcare Price Transparency Tool: Who Uses It, and How They Shop for Care (Health Affairs, April 2016)
- Health Savings Account-Eligible High Deductible Health Plans: Updating the Definition of Prevention (University of Michigan Center for Value-Based Insurance Design, May 14, 2014)
- Information Letter on ERISA Fiduciary Duty To Consider Quality in Selecting Healthcare Services (DOL, Feb. 19, 1998)

Other Mercer Resources

- Senate Panel OKs Surprise Medical Bill Reforms but Plans Changes (June 27, 2019)
- Executive Order on Transparency, HSAs: What Employers Need To Know (June 27, 2019)

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