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Inflation Reduction Act Includes Health Provisions

Later today the House is expected to approve the Inflation Reduction Act, as passed by the Senate on August 7, and send it to President Biden's desk for his signature. The bill's key health-related provisions would create a new requirement for Medicare to negotiate certain prescription drug prices for Medicare beneficiaries and extend enhanced ACA premium tax credits for three more years.

Medicare Prescription Drug Prices

The bill would require the Secretary of Health and Human Services (HHS) to establish a Medicare Drug Price Negotiation Program for certain "high-priced" single-source drugs. In general, under the program selected drugs would be provided to participants in Medicare Part B, Part D, and Medicare Advantage Prescription Drug (MA-PD) Plans at the "Maximum Fair Price" negotiated by HHS and the manufacturer. The program would be established in 2023, but the application of the Maximum Fair Price to selected drugs would not begin until 2026.

The bill would establish specific criteria for selecting drugs that would be subject to negotiation. For each "initial price applicability year," HHS would be required to identify and publish a list of negotiation-eligible drugs. For the 2026 initial price applicability year, only up to 10 drugs would be negotiation-eligible. That limit would increase to 15 in 2027 and 2028, and to 20 in 2029 and beyond. Only certain single-source drugs that are among the 50 highest expenditure drugs under Part B or Part D could be negotiation-eligible, subject to exceptions for small biotech drugs and orphan drugs, among others.

HHS also would be required to publish the Maximum Fair Price that it negotiates with the manufacturer for each selected drug.

While these provisions may result in Medicare beneficiaries paying less for certain prescription drugs, the impact on other payers – including group health plans – remains unclear.

The bill also would:

- Cap Medicare patients' out-of-pocket prescription drug costs at $2,000 per year; and
- Require drug companies to provide rebates to Medicare to the extent they increase prices faster than inflation

Enhanced ACA Premium Tax Credits

The bill also would extend, through 2025, the enhanced premium tax credits enacted as part of the American Rescue Plan Act (ARPA) of 2021. This means otherwise eligible individuals who purchase the second lowest cost silver plan on an ACA marketplace would continue to qualify for premium tax credits equal to 100% of their premium cost if their household incomes do not exceed 150% of the federal poverty level. Those with household incomes of at least 400% of the federal poverty level would not have to pay more than 8.5% of their incomes for this same coverage.

Without this extension, the pre-ARPA rules would have returned in 2023. Under those rules, premium tax credits are not available to those with household incomes less than 100% or more than 400% of the federal poverty level.

Insulin Safe Harbor for HDHPs

Also of note, the bill would create a new safe harbor permitting HSA-compatible high-deductible health plans (HDHPs) to provide below-the-deductible coverage for insulin. The statutory safe harbor would enhance previous IRS guidance allowing HDHPs to treat insulin as "preventive care" in certain circumstances.

Look for more information about the Inflation Protection Act in future editions of Rewards Policy Insider.

HHS Clarifies HIPAA Privacy Rule Requirements Relating to Disclosures of PHI Involving Reproductive Health

Concerns about states using civil and criminal penalties to enforce abortion restrictions prompted the Department of Health and Human Services' Office of Civil Rights to issue guidance clarifying the circumstances under which HIPAA covered entities may voluntarily disclose an individual's protected health information, or be required to do so.

Background

In general, the HIPAA privacy rule limits how covered entities – i.e., health care providers, health plans, and health care clearinghouses – can use and disclose an individual's protected health information (PHI). Unless an individual gives the covered entity permission to disclose their PHI, disclosure is permitted only if one or more very limited exceptions apply.

Some of the exceptions that might come into play if states are seeking information about individuals aborting pregnancies are:

- disclosures required by law,
- disclosures for law enforcement purposes, and
- disclosures to avert a serious threat to health and safety.

Note that these and other exceptions allow covered entities to disclose PHI without the individual's consent. The HIPAA privacy rule does not require disclosure in any of these circumstances, but the exceptions give covered entities the ability to comply with other laws that might require disclosure without also violating the privacy rule.

As discussed below, the HHS guidance specifically discusses how these exceptions would apply to health care providers that might face questions about disclosing information about abortions that are imminent, or have

already been performed. However, the principles enunciated in the guidance are equally applicable to other covered entities – including group health plans – that might also face these issues going forward.

Disclosures Required by Law

According to the HHS guidance, covered entities may disclose PHI without the individual's consent if the disclosure is pursuant to "a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law." The permitted disclosure is limited to what the law requires.

To illustrate, the HHS guidance provides the following example:

> An individual goes to a hospital emergency department while experiencing complications related to a miscarriage during the tenth week of pregnancy. A hospital workforce member suspects the individual of having taken medication to end their pregnancy. State or other law prohibits abortion after six weeks of pregnancy but does not require the hospital to report individuals to law enforcement. Where state law does not expressly require such reporting, the Privacy Rule would not permit a disclosure to law enforcement under the "required by law" permission. Therefore, such a disclosure would be impermissible and constitute a breach of unsecured PHI requiring notification to HHS and the individual affected.

Disclosures for Law Enforcement Purposes

Permitted disclosures for law enforcement purposes must be "pursuant to process and as otherwise required by law," according to the HHS guidance. In other words, the law enforcement request must be made through a legal process such as a court order or court-ordered warrant, a subpoena or summons. If there is no mandate that is enforceable in court, this exception is not available.

For example, if a law enforcement officer goes to an abortion clinic or hospital and asks for records of abortions performed, the disclosure exception would not apply unless the request is accompanied by a court order or other legally enforceable mandate.

Disclosures to Avert a Serious Threat to Health and Safety

This exception applies "if the covered entity, in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and the disclosure is to a person or persons who are reasonably able to prevent or lessen the threat." Additionally, the disclosure must be consistent with applicable law and any relevant standards of ethical conduct.

The HHS guidance states this exception generally would not be available for disclosures of PHI relating to an individual's intent to get an abortion. The reason is that abortion does not pose a serious and imminent threat to health or safety, and such disclosure generally would be inconsistent with professional ethical standards.

The text of the HHS guidance is available here.

COVID-19 Public Health Emergency Extended Again

Once again U.S. Secretary of Health and Human Services Xavier Becerra has extended the COVID-19 Public Health Emergency (PHE) for 90-days, effective July 15, 2022. For group health plans, the extension means mandates relating to coverage of COVID-19 testing and vaccinations will continue at least through mid-October. By mid-August, we should know if the PHE will be extended through January 2023.

Coverage Mandates

The Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act established certain mandates for group health plans regarding coverage of COVID-19 testing and vaccinations that will remain in effect until the COVID-19 PHE ends.

In general, plans must cover COVID-19 tests and testing-related services without any cost-sharing, prior authorization, or other medical management requirements. Since mid-January of this year, this requirement has extended to over-the-counter, at-home tests.

Additionally, plans must cover COVID-19 vaccines provided by out-of-network providers without cost-sharing. In general, plans must use the Medicare reimbursement rate for purposes of reimbursing out-of-network providers for the cost of administering the vaccine. The costs of the vaccine itself are still being paid by the federal government.

As noted, these mandates will remain in effect until the COVID-19 PHE ends.

When will the PHE End?

As discussed, Secretary Becerra extended the public health emergency for another 90-days effective July 15, 2022. That means the public health emergency is currently scheduled to remain in effect at least until October 13, 2022.

Whether Secretary Becerra will extend the public health emergency again or let it expire in mid-October is an open question. Some political pressure is building for both the public health emergency and the COVID-19 National Emergency to end. But there is more at stake than just these group health plan mandates. Also tied to the public health emergency are special rules for Medicare and Medicaid, as well as the validity of Emergency Use Authorizations issued by the Food and Drug Administration.

Secretary Becerra has indicated that he will give at least 60 days advance notice if he plans not to extend the public health emergency. That means a decision will need to be made in mid-August if he is not going to renew it in mid-October.

Note that the Public Health Emergency is different from the COVID-19 National Emergency, which is currently in effect through February 2023. The "outbreak period" relief for COBRA election and premium payment deadlines, among other ERISA requirements for group health plans, is tied to the National Emergency declaration. See Rewards Policy Insider 2022-5, March 11, 2022, for more on the National Emergency declaration and related outbreak period relief.

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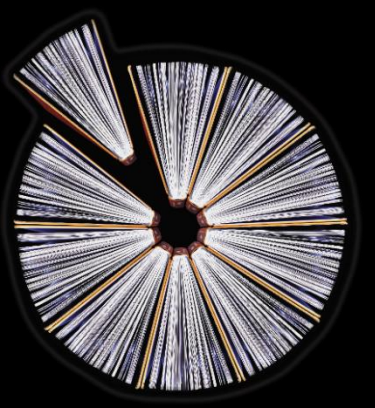

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