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I. AFFORDABLE CARE ACT AND INSURANCE COVERAGE ISSUES

U.S. Health-coverage Barriers Persist for Transgender People Despite Law Protections

(Regulatory Intelligence) - Insurance coverage barriers continue to obstruct access to healthcare for transgender people in the United States, even after the Biden administration said it would apply the Affordable Care Act's anti-discrimination provisions to issues of gender identity and sexual orientation. A patchwork of state initiatives, ranging from categorical restrictions on coverage to mandates for coverage, complicate the issue for consumers and insurers. [FN2]

A recent court ruling in Iowa upholding the state's nondiscrimination provisions and paving the way for coverage for gender-transitioning surgery in its Medicaid program may help reinforce health coverage protections in more parts of the country, experts and advocates said. It could also bolster similar lawsuits seeking to ensure Medicaid-program coverage for low-income transgender Americans.

Advocates are also pushing for states to add more explicit guidance for coverage of care related to gender transition in private insurance and federal-state administered Medicaid plans. The aim is to prevent coverage denials rooted in continuing debates over which treatments are ‘medically necessary” or conform to accepted standards of medicine.

The Affordable Care Act's Section 1557 bars healthcare discrimination based on sex, but its interpretation has varied as administrations have sparred over its inclusion of individuals who identify as transgender or non-binary. The U.S. Department of Health and Human Services under former President Donald Trump said it would treat gender discrimination based on the biological sex assigned at birth -- either male or female -- and not enforce protections against discrimination based on gender identity or cases where individuals identified differently from the sex assigned to them at birth.

The health agency reversed that stance in May and is working on new rules to clarify the provision.

About 11.3 percent of U.S. LGBT adults identified as transgender individuals, a Gallup survey showed in February this year. Gallup estimated transgender individuals represent about 0.6 percent of the U.S. adult population.

Patchwork of state laws

Despite the ACA protections, healthcare coverage for transgender people is usually regulated by individual states - the main regulators of health insurance in the United States.

Twenty-seven states and four U.S. territories lack any explicit insurance protections for transgender people, according to data from Movement Advancement Project (MAP), a nonprofit think tank. Arkansas specifically permits insurers to refuse gender-confirmation care, such as surgeries to alter the physical appearance in line with the patient's gender identity.

An Ohio law that took effect in September, seen as hostile to the coverage needs of transgender people, allows providers to deny care and insurers to refuse payment when the services violate their ‘conscience as informed by the moral, ethical, or religious beliefs or principles held by the practitioner, institution, or payer.’ Transgender people in such jurisdictions often depend on insurers to voluntarily comply with the ACA's provisions, or they attempt to relocate to a state with stronger protections or forego care altogether, experts said.

The number of insurance plans with blanket exclusions for coverage of gender-identity related care has decreased over the last five years and is expected to continue to fall, as a result of the HHS' updated interpretation of the ACA's Section 1557 protections.

However, many policy gaps need to be filled to address the existing barriers to coverage of gender-transitioning surgeries and complementary care, advocates said.

'Unfortunately, there are still plans that include exclusions that limit access to medically necessary treatment," said Sharita Gruberg, vice president for the LGBTQ+ Research and Communications Project at the Center for American Progress. 'There is definitely a serious lag between what the law says and what insurers are actually covering."

About 46 percent of transgender individuals surveyed said they had faced an insurance denial in 2020 for gender-affirming care, a study by the policy institute showed. For transgender people of color, the rate of denial was higher at 56 percent.

Those denied claims can appeal to the insurer, complain to the state regulator, call for an independent medical review or sue the insurer. Often insurance denials are reversed after the consumer seeks a review at some level but the process is time-consuming and lack of awareness about these options and inability to afford high-cost treatments leads to many individuals foregoing medically necessary care, experts said.

Health insurance industry group America's Health Insurance Plans has said insurers have largely covered medically necessary care and preventive services for transgender individuals since Section 1557 went into effect in 2017. However, 'some markets may still be catching up," it said.

'Exact coverage and benefits will vary depending on the provider, the individual, their health plan, and local market dynamics," said David Allen, spokesperson for the group.

State laws lack guidance on 'medically necessary" care

States that prohibit exclusions for coverage of transgender healthcare, in private insurance and Medicaid programs, require insurers to cover care for transgender people as they would for cisgender individuals ? those whose gender identity matches the one they were assigned at birth.

These laws, however, sometimes lack explicit language over what medical treatment and services must be covered, leading to denials, as 'cosmetic treatments," for gender-confirming procedures that have nonetheless been classified as 'medically necessary, life-saving treatment" for transgender people.

Treatment for gender dysphoria -- a condition where a person experiences physical and psychological distress due to a mismatch between their biological sex and the gender they identify with ? could require gender-transitioning surgery and hormonal therapy accompanied by counseling and multiple procedures, such as breast reconstruction or facial feminization surgeries.

Transgender individuals have reported being denied treatments such as voice and hormone therapy or fertility preservation, among other treatments, experts said. Some transgender people have reported being denied coverage for preventive care such as prostate exams or mammograms because the insurer's record did not classify them as eligible for the treatment based on their gender.

In general, associations and experts support gender-confirming surgeries for individuals with gender dysphoria. The World Professional Association for Transgender Health (WPATH) states that based on 'clinical and peer-reviewed evidence that gender-affirming/ confirming treatments and surgical procedures ... have proven to be beneficial and effective in the treatment of an individual with transsexualism or gender dysphoria.' These surgeries 'play an undisputed role in contributing toward favorable outcomes.'

Similarly, a study published by the American Psychiatric Association found that transgender people who received gender-confirming surgery had significantly less need for mental health treatment over time. The study's authors said their findings supported the 'decision to provide gender-affirming surgeries to transgender individuals who seek them.'

State insurance-regulator bulletins that clarify the scope of coverage can go a long way in reducing coverage denials, said Sasha Buchert, senior attorney at Lambda Legal, an LGBTQ rights advocate. 'Having the state come along and categorically clarify that that's not going to be the practice they're going to tolerate has been really helpful. So places where they don't have bulletins are what I would point to as the most concerning."

Colorado has sought to improve protections by requiring, under its essential health benefits (EHB) benchmark marketplace insurance plan, coverage of all gender-affirming care for people who need it.

The Washington state legislature passed the Gender Affirming Treatment Act earlier this year preventing insurers from imposing 'cosmetic"-based exclusions for commonly prescribed gender-affirming treatments. The bill is effective for policies issued on or after January 1, 2022.

Medicaid program exclusions

The federal-state Medicaid program plays a crucial role in healthcare access for transgender people, who are more likely than the population as a whole to live below the poverty line.

'It's hard for trans folks to find employment altogether and much less meaningful employment that covers that provides good health care coverage. So, a lot of trans people disproportionately turn to Medicaid for their coverage," Buchert said. 'When states opt not to expand Medicaid offered by the ACA — a lot of folks have a hard time getting covered even under Medicaid in those in those places."

States receiving federal funds for their Medicaid expansion programs are mandated to comply with Section 1557, but data from MAP shows 10 states explicitly exclude gender-confirming care under their state Medicaid programs. About a dozen states have rejected Affordable Care Act provisions enabling them to expand their Medicaid programs.

An Iowa court ruled last month that a state law preventing its Medicaid program from covering gender-confirming surgery violated the Iowa Civil Rights Act and the state's constitution. Advocates for transgender people's rights hope related cases in other states like West Virginia, Arizona and Wisconsin will see a similar outcome.

'Ideally, the [other] states would look at what happened in Iowa and affirmatively brings their own Medicaid coverage rules into compliance. But in the event that that does not happen, I feel pretty confident that the courts will find that the ACA prohibits those kinds of blanket bans," Gruberg said.

Taylor Brown, lead counsel on a similar case in Georgia brought by the American Civil Liberties Union (ACLU) also said the Iowa court ruling could be a 'good sign." However, she expressed concern that claims denials for transgender people continue to be seen even in states that allow for coverage of transition-related treatment.

Rights advocates are looking to bring a wave of new cases to address these exclusions for coverage of secondary care, Brown said.

'Although we see Medicaid programs expanding coverage to include gender-affirming health care, there are still exclusions within those coverage provisions," Brown said.

U.S. Agency Proposes Rule to Restore Health Insurance Protections for LGBT Individuals

(Regulatory Intelligence) - The Biden administration has proposed a rule that would explicitly prohibit health insurers from discriminating on the basis of sexual orientation and gender identity, restoring key health coverage protections for the LGBT+ community, especially transgender individuals. [FN3]

The U.S. Department of Health and Human Services last week proposed adding 'gender identity" and 'sexual orientation" to the interpretation of the Affordable Care Act's Section 1557, which prohibits discrimination on the basis of sex. The proposed rule reverses the previous administration's policy of restricting sex-based discrimination findings to those who faced discrimination for being male or female.

The latest move is part of the administration's effort to combat discrimination against people who identify differently from the sex assigned to them at birth. Last January, President Joe Biden issued an executive order directing the HHS to review all existing regulations and agency actions to determine consistency with the administration's policy.

The rule is 'part of the Biden-Harris Administration's ongoing efforts to ensure an equitable health care system," said Health and Human Services Secretary Xavier Becerra.

Despite the administration's revised stance, members of the LGBT community have reported facing claims denials for healthcare procedures that have been covered for cisgender individuals.

In a case unrelated case (Bostock v. Clayton County) in 2020, the U.S. Supreme Court held that federal prohibitions on sex discrimination would include discrimination based on sexual orientation and gender identity.

The proposed rule would bring much-needed clarity on the rights of transgender consumers and the responsibilities of insurers, said Sharita Gruberg, vice president for the LGBTQI+ Research and Communications Project at American Progress, a think tank.

A spokesperson for America's Health Insurance Plans, a health insurance group, did not respond to a request for comment.

Health Insurers Required to Cover 8 At-home COVID-19 Tests Each Month

(Regulatory Intelligence) - Amid surging Omicron cases across the country, health insurers will be required to cover at least eight at-home COVID-19 tests per individual, each month, without an order from a healthcare provider, the Centers for Medicare and Medicaid said on Monday. [FN4]

Insurers will have to comply with the new requirement starting Jan. 15 and pay or reimburse up to $12 per at-home test kit purchased by their policyholders. Consumers will also be entitled to insurance coverage of unlimited laboratory tests or at-home tests ordered by a healthcare provider. At-home test kits are largely priced between $14 to $26 for a kit consisting of two tests. High demand and price gouging however has led to a shortage and consumers have reportedly paid as much as $75 per kit, mainly from resellers.

'Testing is critically important to help reduce the spread of COVID-19, as well as to quickly diagnose COVID-19 so that it can be effectively treated. Today's action further removes financial barriers and expands access to COVID-19 tests for millions of people," CMS' Administrator Chiquita Brooks-LaSure said.

The administration said it will allow insurers and group health plans to make the over-the-counter tests available to consumers through preferred pharmacies, retailers or other entities without any out-of-pocket cost, but still require the $12 price reimbursement if the individual chooses to purchase elsewhere.

'This is all part of our overall strategy to ramp up access to easy-to-use, at-home tests at no cost," said Secretary of the U.S. Department of Health and Human Services Xavier Becerra.

The announcement adds much-sought clarity to the words of President Joe Biden who earlier this month said his administration will require coverage of the rapid testing kits available over-the-counter but did not specify details.

America's Health Insurance Plans, a group of health insurers, said providers will work ‘as quickly as possible” to implement the guidance in ways that would limit confusion and challenges to the consumer. ‘While there will likely be some hiccups in early days, we will work with the Administration to swiftly address issues as they arise,” said Matt Eyles, CEO of AHIP.

State Medicaid programs and the Children's Health Insurance Program (CHIP) programs are already required to cover FDA-authorized at-home COVID-19 tests without any cost-sharing. Consumers without insurance can avail of free tests from the government program that will make 500 million tests available to people, expected at the end of January.

U.S. Health Agency Proposes Rule to Reduce Out-of-Pocket Prescription Drug Costs; Improve Consumer Protections

(Regulatory Intelligence) - The Centers for Medicare & Medicaid Services (CMS) has moved to lower out-of-pocket Medicare Part D prescription drug costs as well as improve consumer protections, reduce disparities and ‘improve health equity’ in Medicare Advantage and Medicare Part D plans. The moves were outlined in the agency's contract year 2023 Medicare Advantage and Part D proposed rule for public inspection last week. [FN5]

More than 27 million beneficiaries are enrolled in Medicare Advantage according to CMS. Medicare Advantage plans are managed-care plans offered through private insurers that provide Part A (in-patient) and Part B (out-patient) coverage. They often also include Part D prescription drug coverage. An additional 24 million beneficiaries are enrolled in standalone Part D plans. There are also an increasing number of individuals in Medicare Advantage plans who are dually eligible for Medicare and Medicaid coverage.

Lowering out-of-pocket drug costs

The negotiated price a Part D plan pays for a drug is the price it reports to CMS at the point of sale. It is also the price used to calculate beneficiary cost-sharing. However, some Part D plans are entering into arrangements with pharmacies to pay less for dispensed drugs if the pharmacies do not meet certain criteria. As a result of these arrangements, the ‘negotiated price is frequently higher than the final payment to pharmacies.’ The higher negotiated price also means that the beneficiary pays more in cost-sharing and max out the Part D benefit more quickly.

Under the proposed rule, CMS would redefine the negotiated price as the lowest possible payment to a pharmacy, effective January 1, 2023. This would reduce beneficiary out-of-pocket costs, improve price transparency and increase market competition in the Part D program.

Marketing and communications

CMS is also proposing changes to ensure Medicare beneficiaries receive accurate and accessible information about Medicare coverage. The proposed rules would strengthen CMS oversight of third-party marketing organizations ‘to detect and prevent the use of deceptive marketing tactics to enroll beneficiaries' in Medicare Advantage and Part D plans. The proposed rule would also reinstate the ‘inclusion of a multi-language insert’ in specified materials to information beneficiaries about free language and translations services. It would also codify enrollee ID card standards, add requirements related to disclaimer for limited access to preferred cost-sharing pharmacies and include new required information on plan websites.

Medical loss reporting

CMS is also proposing to reinstate medical loss ratio requirements that were in effect for contract years 2014-2017. Under the Affordable Care Act, insurance companies must spend 80% or 85% of premium dollars on medical care. Current regulations require Medicare Advantage and Part D plans to report the percentage of revenue spent on patient care and quality improvements as well as the ‘amount of any remittance that must be paid to CMS for failure to meet’ the 85% minimum medical loss ratio requirement. The proposed rule would require Medicare Advantage and Part D plans to ‘report the underlying cost and revenue information’ necessary to calculate and verify the medical loss ratio percentage and the remittance amount.

Network adequacy

CMS is also proposing to require Medicare Advantage plan applicants to ‘demonstrate they have a sufficient network of contracted providers' before CMS will approve an application for a new or expanded Medicare Advantage plan. CMS expects this to strengthen its oversight of a plan's ability to provide an adequate network of providers to deliver care to plan enrollees. The requirement will also provide Medicare Advantage plans with information on network adequacy prior to their application. This should reduce late changes to bids that might affect the bid pricing tool. Recognizing the challenges the timing change might create for plans, CMS is also proposing a to ‘allow a 10-percentage point credit’ toward the percentage of beneficiaries residing within published time and distance standards for new or expanding service area applicants. However, after the coverage year starts, the credit would no longer apply and plans would have to be in full compliance with network adequacy requirements.

Beneficiary protections

CMS also proposes an number of changes intended to provide additional protections for beneficiaries in Medicare Advantage and Part D plans. Under the proposed rule, CMS could deny a new contract or service area expansion for plans that receive a 2.5 or lower star rating, declare or file for bankruptcy or that exceed a CMS designated threshold for compliance actions. CMS also proposes to require

special needs plans to add specific standardized questions to their health risk assessments relating to housing stability, food security and access to transportation. The proposed rule would also require dual eligible special needs plans to establish and maintain one or more enrollee advisory committees that the plans consult on 'issues related to health equity.' The proposed rules would also simplify the appeals and grievance process for beneficiaries in a special needs plan, require integrated materials for dually eligible beneficiaries to give them better understand the full scope of benefits available and make changes to the maximum-out-of-pocket limit calculation for dually eligible enrollees.

The proposed rule is schedule for publication in the Federal Register on January 12.

Record 14 million Americans Sign up for Healthcare Since Enrollment Start - Govt

(Reuters) - A record 14.1 million Americans have signed up for health insurance since the start of the 2022 open enrollment period in November, the U.S. health department said on Thursday. [FN6]

The number includes ten million people in the 33 U.S. states using the federal marketplace exchange and about four million people from states that have their own exchanges, the Department of Health and Human Services (HHS) said on a press call.

The enrollment figure, which is as of Jan. 8, represents a 21% increase in plan selections compared with last year.

'I can guarantee the president is all about helping more people get quality insurance coverage,' said HHS Secretary Xavier Becerra in response to a question on whether the government could extend the enrollment deadline.

'I wouldn't be surprised if he instructs us to continue to look for ways to make sure Americans get the coverage they need,' he said.

The open enrollment period started on Nov. 1 and will end on Jan. 15. The government had in September extended the deadline by a month until January to give people more time to review and choose health plans.

'With Omicron, with COVID still here, we have to do everything we can to give people that protection,' Becerra said.

Enrollment on ACA Marketplaces Climb to New High of 14.5 million

(Regulatory Intelligence) - About 14.5 million people have enrolled for health insurance coverage this year on the Affordable Care Act's healthcare exchanges, clocking a new high and a nearly 21 percent increase in sign-ups compared to the open enrollment period last year. More than 10 million people accessed coverage through the federal healthcare exchange, the highest ever enrolment on record, according to President Joe Biden. [FN7]

'This did not happen by accident. The American Rescue Plan did more to lower costs and expand access to health care than any action since the passage of the Affordable Care Act" Biden said in a statement, referring to the coronavirus relief package that expanded healthcare subsidies and capped premiums for more people accessing coverage through the exchanges.

About 3 million new consumers who lacked any form of prior coverage signed up for ACA plans this year, the U.S. Department of Health and Human Services said. About 3.2 million people or 32 percent of consumers signing up on the federal marketplace signed up for plans for $10 or less, per month, after the additional subsidies provided by the Biden administration's COVID relief package.

Deductibles were less than $1000 for the majority of consumers who signed up for coverage on HealthCare.gov, which provides access to ACA plans in 33 states that do not have their own marketplaces. Employer deductibles have averaged $1400 over the same period, the HHS said.

Besides economic relief, the Biden administration also reversed funding cuts made by the previous administration for outreach efforts and extended the open enrollment period until Jan 15. The open enrollment period beginning Nov 1 each year was closed in six weeks from its start by the Trump administration. About 12 million people signed up for ACA coverage last year.

'The record-breaking number of enrollments during this marketplace open enrollment period really sends a clear message when we invest in health care and make it affordable, people sign up," Centers for Medicare and Medicaid Services Administrator Chiquita Brooks-LaSure said on a call with reporters.

The enrollment period continues to remain open in five state marketplaces and Washington DC and the final numbers could increase 'substantially above" the 14.5 million people who have already enrolled, according to HHS Secretary, Xavier Becerra.

'We are seeing more Americans with insurance today. And we're seeing fewer Americans who are uninsured today. Those are all arrows heading in the right direction," Becerra said on the call.

The uninsured rate for the U.S. population dropped to 8.9 percent in the third quarter of 2021 from 10.3 percent for the last quarter of 2020, resulting in about 4.6 million additional people gaining coverage over the previous year, a report from the HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) said.

The largest coverage gains were seen among people with incomes under 200 percent of the federal poverty level currently at roughly $27,000 for a single adult or $56,000 for a family of four.

Biden Urges Expansion of Health Coverage in State of the Union Speech

(Regulatory Intelligence) - U.S. President Joe Biden renewed his call to make pandemic-related health insurance subsidies permanent while advocating for the expansion of transgender and women's healthcare rights in his State of the Union address on Tuesday. He also called on reining in the cost of prescription drugs like insulin and for parity in mental and physical health coverage. [FN8]

'The American Rescue Plan is helping millions of families on Affordable Care Act plans save $2,400 a year on their health care premiums. Let's close the coverage gap and make those savings permanent," he said in his speech to the joint session of Congress.

Biden's COVID-19 relief package, the American Rescue Plan Act, passed in March last year increased subsidies to purchase health insurance on the individual market while widening eligibility criteria to receive it. These provisions are set to end in 2022.

Health insurers 'strongly support" making the premium savings in the law permanent to improve insurance affordability and accessibility across the country, according to a statement from American Health Insurance Plans (AHIP), a trade group.

Calls to cap insulin costs, insurers push back

Biden also called on Congress to cap the cost of insulin at $35 a month to improve affordability for all insured patients with diabetes. Politicians on both sides of the aisle agree on the need to rein in the cost of insulin ? a life-saving drug for people with diabetes that costs about $375 on average and varies by usage ? but disagree on whether the cap should be extended to those privately insured.

The most recent attempt to cap co-pays on insulin for all was shot down in December as the broader Build Back Better Plan of which it was a part, failed to garner adequate support to pass through the Senate. Senate Majority Leader Chuck Schumer said he will hold a Senate vote in March on the Affordable Insulin Now Act, a standalone bill to cap insulin costs. The probability of its passage remains uncertain as it applies to private insurance and Medicare.

AHIP said Biden's call to impose caps on co-pays without addressing underlying drug price increases by manufacturers will only raise the cost of health insurance and other copays for consumers and businesses. 'We must hold drug manufacturers accountable and not give them a free pass to raise insulin prices every single year," the group of health insurers said following the president's speech.

Insurers have earlier argued that copay caps on insulin would give drugmakers unhinged power to raise prices which will then get passed on to the consumer in the form of higher premiums and other out-of-pocket costs.

Protect healthcare rights for women, transgender community

Biden also took aim at recent restrictive state laws targeting women's abortion rights, the transgender community and gender-affirming treatments in his address.

'Advancing liberty and justice also requires protecting the rights of women," Biden said, referring to protecting the precedent set in Roe v. Wade, in which the U.S. Supreme Court allowed abortions until fetal viability or about 26 weeks. 'If we want to go forward—not backward—we must protect access to health care. Preserve a woman's right to choose," he said.

Biden's comments come a day after the U.S. Senate failed to pass the Women's Health Protection Act that aimed to protect a woman's right to abortion due to Republican opposition. A SCOTUS ruling is also pending in a case over the Mississippi law that aims to ban abortion after 15 weeks. Texas' law that restricts abortion after 6 weeks, enforced by private citizens, has also been in effect for six months, although it is subject to several lawsuits.

'We are at a breaking point for reproductive freedom, and we need lawmakers at all levels of government to act," said Alexis McGill Johnson, president, Planned Parenthood Action Fund. Planned Parenthood Federation of America and more than 100 other reproductive health, rights, and justice organizations urged Biden in a letter earlier this month to address the restrictions on abortion rights in his State of the Union address.

Biden also called on lawmakers to pass the Equality Act that expands civil rights and nondiscrimination protections to the LGBTQ+ community, which has received some bipartisan support.

Transgender people have been subject to recent new state laws and policies that are seen as discriminatory in health care. Texas recently directed that 'sex-change procedures" or so-called gender-affirming treatments in adolescents constitute child abuse. Texas has begun investigating parents who work with medical professionals to provide their children with gender-affirming care, rights organizations Lambda Legal, the American Civil Liberties Union (ACLU), and ACLU of Texas said in a lawsuit directed at state Governor Greg Abbott and another state health official.

Health agencies have ruled gender-affirming care as medically necessary to treat gender dysphoria or significant physical and psychological distress due to a mismatch between an individual's biological sex and the gender they identify with. Transgender adolescents have been found to be at higher risk of mental health problems and even suicide if left untreated.

Expansion of mental health services

Biden also called for full parity between mental and physical health care. 'Let's get all Americans the mental health services they need. More people they can turn to for help," he said.

The president said there was a mental health crisis among children as a result of the pandemic and break from school and routine activities, as cited in a U.S. Surgeon General advisory in December.

Insurers also said they support the call to improve access to behavioral health care, particularly in under-represented and under-served communities. ‘We strongly support parity in coverage for physical and behavioral health needs, expanded access to telehealth services, and driving value-based care arrangements that include behavioral health providers and services,” AHIP said.

COVID Public Health Emergency to be Extended but Concerns Over Uninsured Linger

(Regulatory Intelligence) - The Biden Administration let lapse a deadline for providing a 60-day notice for ending the nationwide public health emergency related to COVID-19, meaning there will be at least one more extension to the ongoing emergency which had been slated to end July 15. The administration's inaction on the deadline forestalls a sudden spike in the numbers of uninsured Americans, but insurers and regulators will still be closely watching for an extension of the Affordable Care Act's expanded premium subsidies as concerns over affordability linger. [FN9]

Health and industry experts had expected the U.S. Department of Health and Human Services to allow its emergency declaration ? in force since January 2020 ? to lapse after the latest 90-day extension announced in April. The end of the emergency would result in about 13 million people losing government-backed health coverage, according to Urban Institute, and tighter rules over COVID-19 vaccines, diagnosis and treatment options, pre-authorizations and telehealth.

Healthcare associations such as the American Hospital Association, American Medical Association, American Nurses Association and the American Association of Retired Persons (AARP), among others requested the administration to maintain the PHE until it is ‘clear that the global pandemic has receded and the capabilities authorized by the emergency declaration are no longer necessary.”

One category expected to be worst hit by the pandemic is low and middle-income enrollees who gained or continued coverage through Medicaid as eligibility checks were suspended during the health emergency. Enrollment in Medicaid expansion plans surged to a historical level of 21 million this year.

One category expected to be worst hit by the pandemic is low and middle-income enrollees who gained or continued coverage through Medicaid as eligibility checks were suspended during the health emergency. Enrollment in Medicaid expansion plans surged to a historical level of 21 million this year.

Many states will re-determine coverage eligibility once the PHE expires, resulting in burdens on patients and the health care system, the associations said in a letter to the HHS. The groups estimated affordability concerns could cause up to 15 million Americans, including 6.7 million children, to lose their coverage.

'There are very significant backlogs in the healthcare system. Many of those affected by these decisions may be economically disadvantaged,” said Mark Halford, senior vice president of life sciences and healthcare, at WNS - a business process management firm. ‘The financial aspects surely do not allow indefinite extension of the PHE and, whenever it ends, there is an enormous administrative challenge to ensure that millions of Americans are not left without cover.”

Eyes on ACA premium subsidies as 2023 rates are set

The American Rescue Plan Act's (ARPA) premium tax credits and premium subsidies helped coverage related to the Affordable Care Act, including Medicaid, surge to 35 million people this year. This premium assistance is set to expire on Dec. 31 but Democrats in Congress have expressed a desire to make some or all of the subsidies permanent.

The uncertainty around the extension of the subsidies is key as insurers are currently in the process of setting and fixing rates for the 2023 coverage year.

'It is possible that some insurers will price 2023 plans a bit higher than they otherwise would, simply because of uncertainty around the future of the ARPA's enhanced subsidies,” policy analysts at KFF, a healthcare data provider, said. ‘Premiums for 2023 are locked in by this August, so if Congress does not act before its August recess, whatever assumptions insurers make about the future of ARPA subsidies will be locked into their 2023 premiums.”

If Congress allows this deadline to pass, the lowest income enrollees could see their premiums increase to $26 from less than $1 per month and the highest income enrollees could see their premiums rise by about 36 percent, according to the healthcare groups. Some consumers will no longer qualify for tax credits at all, forcing people to drop marketplace coverage and possibly become uninsured, they warned.

The National Association of Insurance Commissioners (NAIC) has urged Congress to act by July to extend the enhanced premium tax credits beyond their current end date as resulting premium spikes could lead consumers to drop coverage.

'Those most likely to drop coverage due to higher out-of-pocket premiums are the healthiest enrollees, so risk pools are likely to worsen under these scenarios. These changes would not only affect access to coverage for millions, they would roil insurance markets as issuers and regulators adjust to a likely smaller and somewhat higher-risk overall individual market,” the group of regulators said in a recent letter to Congress.

U.S. Health Insurers Face Compliance, Legal Roadblocks after Roe v Wade Abortion Reversal

(Regulatory Intelligence) - The U.S. Supreme Court's decision to overturn a long-standing precedent upholding a woman's right to abortion allows states to now determine women's reproductive rights, creating a new and rapidly evolving patchwork of policy in the

country. New laws on abortion access could make health insurers vulnerable to compliance and legal hurdles, including exposure to potential criminal liability. [FN10]

The court's 5-4 decision overturning the 1973 protections of Roe v. Wade was part of a 6-3 ruling that upheld a Mississippi ban on abortion after 15 weeks. The ruling on Friday also confirmed the expected outcome after a draft opinion in the case was leaked in May.

The formal decision has accelerated a wave of aggressive state policymaking restricting or easing access to abortions that started after the leaked draft indicated the court was inclined to undermine Roe's federal protection of the right to abortion until fetal viability or about 24 weeks. About 13 so-called ‘trigger laws” were designed to go into effect instantly or at short notice from a reversal of Roe, according to the Guttmacher Institute.

Within hours of the court ruling, Missouri announced an end to all elective abortions in the state, Alabama, Oklahoma, Arkansas and Kentucky enforced or sought to enforce laws that deem performing an abortion at any stage a felony, except where the mother's life is in danger. Utah also prohibited all elective abortions except in cases of rape, incest or medical emergencies.

South Carolina took steps to push a ban on abortion after six weeks or the detection of the fetal heartbeat, while Virginia aimed to restrict abortion after 15 weeks.

The reproductive rights organization said about 26 states are certain or likely to move quickly to ban abortion. In response to these new laws, Minnesota and California passed new protections for people seeking and providing abortions in the state, and New York enacted similar protections in May.

America's Health Insurance Plans, a trade group, said the ruling represented ‘a fundamental change in the way abortion services are regulated” in the country.

Coverage Maze for Insurers

Health insurers in the country must prepare to navigate a compliance maze as the legal landscape over abortion rights evolves rapidly across states.

Insurers must also prepare to face litigation over coverage and wrongful denials and potential lawsuits over liability where abortion is criminalized, experts have said. Insurers are not immune to criminal liability in states, and industry watchers have warned of states with restrictive access potentially targeting insurers for covering an abortion.

Only six states in the country currently have laws requiring abortion coverage in private health insurance plans, of which only 3 require coverage without any co-payments, according to data from Guttmacher.

Health plans and their telehealth benefits will also be at the heart of the fiercely brewing debate over coverage of abortion pills, mifepristone and misoprostol through telehealth services covered in their plans.

Advocates fear these growing consequences for health insurers may further discourage already scant abortion coverage in private health plans.

Those still providing coverage will be under pressure to expand their networks across state lines as a surge in traffic is expected in patients traveling across states to receive abortion services. Many large employers have also begun extending travel reimbursement and abortion coverage benefits to their employees in self-insured plans administrated by third-party insurers.

AHIP said insurers ‘support and promote women's health” and will work with federal and state policymakers, employers and local health care leaders to provide coverage that ‘best meet the local needs, rules, and regulations in states and communities across the country.”

Democrats' Policy Package to Include Prescription Drug Cost Controls and ACA Fix

(Reuters) - U.S. Senate Majority Leader Chuck Schumer said on Tuesday that prescription drug cost controls and an Obamacare fix are the components Democrats will seek for now in a fast-track domestic policy bill. [FN11]

'The two things we want to do in reconciliation, that we're going to do in reconciliation, are prescription drugs and a two-year extension of ACA,' Schumer told reporters.

'ACA' refers to the Affordable Care Act, commonly known as Obamacare.

Democrats are seeking to keep in place increased financial assistance for people who qualify for subsidized health insurance under ACA. The premium relief was offered as part of the American Rescue Plan enacted in 2021, but is set to expire this year, which would result in stark premium increases for millions of people unless Congress acts.

The prescription drug plan would allow Medicare, the government's health plan for senior citizens and the disabled, to negotiate lower prices.

'Reconciliation' refers to an exclusive number of bills that can move through the Senate with a simple majority of support in the 100-member chamber, instead of the 60 votes usually needed.

So far, Schumer has failed to win the backing of Democratic Senator Joe Manchin for a major climate change initiative and tax increases on some corporations as part of such legislation. Without every one of his 50 Democratic caucus members, Schumer does not have the votes to pass bills given solid Republican opposition.

U.S. Says Insurers Must Still Cover Birth Control After Supreme Court Abortion Ruling

(Reuters) - The Biden administration on Thursday warned U.S. businesses and health insurance providers that limiting coverage of contraceptives, after a U.S. Supreme Court ruling that overturned the constitutional right to abortion, would violate federal law. [FN12]

The U.S. Department of Health and Human Services (HHS) issued guidance clarifying that the Affordable Care Act (ACA), commonly known as Obamacare, requires insurance plans to provide free birth control and family-planning counseling to insured individuals and their dependents.

HHS, joined by the U.S. Department of Labor, said it has seen an increase in complaints from women who have been denied coverage for different forms of birth control since the Supreme Court's June ruling.

'With abortion care under attack, it is critical that we ensure birth control is accessible nationwide and that employers and insurers follow the law and provide coverage for it with no additional cost,' HHS Secretary Xavier Becerra said in a statement.

The Supreme Court last month overturned its landmark 1973 decision in Roe v. Wade, which had established a legal right to obtain an abortion.

About half of U.S. states have banned or limited or are expected to ban or curtail abortions as a result of the ruling, and some may also move to restrict access to birth control.

HHS in the guidance issued on Thursday said insurance providers must continue providing coverage for contraceptives even in states that ban them.

The Supreme Court in 1965 said married couples have a constitutional right to buy and use contraceptives, and extended that to unmarried people in a 1972 decision.

But conservative Justice Clarence Thomas wrote in a concurring opinion last month that the court's reasoning in overturning Roe v. Wade could also apply to birth control.

HHS on Thursday said that in 2020, 58 million U.S. women benefited from Obamacare's contraception coverage mandate, saving billions of dollars in out-of-pocket spending.

U.S. Senate's Climate, Health Bill to Reduce Drug Costs for Seniors, Extend ACA Subsidies

(Regulatory Intelligence) - A major climate and health care bill that was passed by the U.S. Senate on Saturday and is expected to become law aims to reduce Medicare prescription-drug costs and out-of-pocket costs for American seniors, as well as extend premium subsidies under the Affordable Care Act health insurance law. [FN13]

The Senate passed the Inflation Reduction Act with Vice President Kamala Harris casting the tie-breaking vote after a 50-50 party line vote, to give President Joe Biden and his fellow Democrats a victory on the bill.

The measure now goes to the U.S. House where Democrats hold a narrow margin and it is expected to pass. Biden has said he will sign the bill.

Medicare drug costs

The bill includes provisions that would reduce Medicare spending on prescription drugs and reduce out-of-pocket costs for American seniors. Under the bill, the Medicare system would have the ability to negotiate for lower prices on 10 drugs beginning in 2026 and would add 15 drugs in both 2027 and 2028. An additional 20 drugs would be added in 2029 for a total of 60 drugs eligible for negotiated pricing under Medicare.

Which drugs are subject to negotiations will be determined based on the ‘total expenditures' for the drugs under Medicare Part B (out-patient coverage) and Part D (prescription drugs) during the prior 12-month period. The negotiated prices would go into effect in 2026 for Part D drugs and 2028 for Part B drugs.

The Pharmaceutical Research and Manufacturers of America (PhRMA) said when the bill was introduced in July that it amounted to ‘sweeping government price-setting policies that will threaten patient access and future innovations.’

The bill also requires drug manufacturers that raise Medicare drug prices more than the rate of general inflation to pay a rebate to Medicare for the amount of the increase that is higher than the general rate of inflation. For Part D drugs, this requirement begins in October. For Part B drugs, it begins in January.

The bill also caps annual cost-sharing under Medicare Advantage and Part D plans in 2025 to $2,000. This will result in significant savings for seniors taking expensive medications. The bill also limits premium increases for Part D plans to no more than 6% a year through at least 2029.

It also includes a $35 out-of-pocket limit on insulin for Medicare beneficiaries. However, Republicans were able to remove a provision that would have imposed the same limit to private health plans too.

Additionally, the bill will make eligible vaccines free for seniors with Medicare Part D.

'With this bill, millions of Americans will see lower health care costs,' Health and Human Services Secretary Xavier Becerra said in a statement after the bill passed. ‘The Inflation Reduction Act locks in premiums that save 13 million people an average of $800 per year. For anyone who relies on Medicare, the bill will put a $2,000 cap on their out-of-pocket costs for the prescription drugs that they need. In addition, it will do something that we have tried ? and failed ? to do in Washington for decades ? allow Medicare to negotiate a better deal on prescription drugs.’

Enhanced ACA premiums

The bill would also extend enhanced Affordable Care Act (ACA) subsidies for an additional three years. The subsidies were increased for 2021 and 2022 under COVID-19 crisis legislation called the American Rescue Plan Act. The increase helped enrollment reach a record 14.5 million in ACA exchanges for 2022. The uninsured rate was also at an all-time low this year. Without the extension, the subsidies would have ended for the 2023 plan year. Enrollment for 2023 begins this November.

The subsidies allowed some low-income enrollees to pay only $0 or $10 per month in premiums.

U.S. Court Ruling on HIV Prevention, Treatment Drugs Shines Light on Coverage Gaps

(Regulatory Intelligence) - A U.S. federal judge in Texas last week threw into uncertainty the future of employer insurance coverage for people at risk of contracting HIV. But even before then, the uptake and coverage of drugs related to HIV prevention and treatment, especially newer injectable drugs, were already deficient and lacking proper enforcement, consumers, employers and public health experts say. [FN14]

When taken as prescribed, so-called PrEP (pre-exposure prophylaxis) drugs for HIV, reduce the chance of transmission from sex by 99 percent and from injection drug use by 74 percent.

An estimated 1.1 million people currently live with HIV/AIDS in the country and though the condition can now be managed with antiretroviral drug treatments, there is still no cure. Prevention remains considered the most effective strategy, and PrEP drugs are considered a vital tool in the nation's effort to combat the AIDS epidemic.

The Texas court ruling upheld the religious freedom of an employer to deny PrEP coverage. It remains unclear whether or how the ruling applies nationwide. Coverage of PrEP drugs is expected to remain unaffected until the court provides more detail. The ruling is widely expected to be appealed.

The plaintiffs in the lawsuit claimed they suffered both religious and economic burdens from having to pay higher premiums to subsidize the cost of expensive HIV prevention drugs. Experts say many patients at high-risk face multiple barriers to access coverage for these drugs, especially newer, more convenient long-acting injectables. The injections need to be administered at monthly intervals instead of the daily oral pill.

'It is beyond ironic. It is the major deficiency in our healthcare system and one that requires a solution that does not become a political football or hostage to insurance industry special interests or judicial activism,” said Jos? Zuniga, president of the International Association of Providers of AIDS Care, a medical professionals group that advocates for better access to treatment of HIV and related illnesses.

'We have been dodging this discussion as a country for quite some time,' he said.

The Affordable Care Act mandates that drugs on a list from the U.S. Preventive Services Task Force (USPSTF), including HIV PrEP drugs, must be free under almost all health insurance plans.

The Biden administration reinforced the need to cover HIV PrEP in July 2021. Still, weak enforcement has led to several complaints of restrictions on coverage or cost-sharing burdens even for oral pills like Truvada and Descovy which are on the preventive care list.

'We have to get it right [on oral PrEP] because we have new long-acting therapies, and if we're not getting it right now, how are we going to get it right for the newer drugs,' said policy advocate Carl Schmid, executive director, HIV+Hepatitis Policy Institute. ‘The future of HIV treatment is long-acting [drugs], and the future of prevention is long-acting. It's better for adherence and people prefer it.’

The preventive services task force is currently reviewing the addition of a long-acting injectable, Apretude approved in Dec 2021, to its list of drugs that must be covered. Several state Medicaid programs have also begun covering the drug without the need for prior authorization.

Some insurance carriers, however, require prior authorization, impose multiple eligibility restrictions of their own on its access or deny coverage of the drug entirely, saying it is not medically necessary.

Schmid pointed to a policy of Blue Cross Blue Shield in Arkansas that requires anyone requesting Apretude to provide evidence, which he called hard to obtain, of non-compliance or intolerance with daily oral PrEP. It also requires negative pregnancy tests from women with reproductive potential. The FDA label does not preclude its use by pregnant women, although the manufacturer's prescribing information said the drug's use in pregnant women has not been evaluated.

Leading insurer United Healthcare's coverage policy for Apretude also requires the patient to have difficulty with adherence to oral PrEP, among other criteria, to be eligible for the injectable drug.

Long-acting drugs sometimes not covered at treatment stage either

Besides preventive drugs, coverage for Cabenuva ? a long-acting injectable HIV treatment approved by the Food and Drug Administration last year, is also subject to utilization management and prior authorization obstacles or denial by many insurers. Many people find the pill-a-day oral regimen hard to adhere to, and access to monthly treatment can help prevent an infection from progressing to AIDS.

Fran Hutchins, executive director of the nonprofit Equality Federation said she has sought in vain to find an insurance plan that will cover Cabenuva for the federation, which advocates for issues faced by the LGBT community.

'For us, the primary issue is not the newness of the drug. It is the lack of transparency and the information asymmetry when it comes to insurance companies and those who are shopping for insurance plans,' said Hutchins. 'It should not be a question. We should not have to wait to get a denial to learn that a plan does not cover this.'

A federation employee said they had sought coverage of Cabenuva since August 2021 but has been consistently denied coverage, to date, as their insurer does not deem the treatment 'medically necessary.'

Employees in other workplaces lacking coverage of the drug may avoid disclosing their concerns or advocating for its inclusion for fear of discrimination over their HIV status, Hutchins said.

'We're definitely seeing more utilization management being implemented by insurance plans across the HIV drug class, said Tim Horn, director of health care access at NASTAD - a non-non-profit group of public health officials who administer HIV programs. 'Insurers, both public and private, need to understand that they play vital roles in strategies to end the HIV epidemic in the U.S.'

Furthermore, Horn said, drug pricing has become an increasingly important consideration affecting access. Manufacturers need to work closely with insurers to ensure coverage of relevant drugs with minimal restrictions.

Beyond the limitations of private insurance, 20 state AIDS drug assistance programs, part of the federal Ryan White HIV/AIDS Program that provides prescription drugs to low-income people without coverage, currently do not cover Cabenuva.

Weak enforcement dampens policy measures, widens access inequities

There has been an uptick in coverage of PrEP pills and injectables since the Biden administration renewed its call for PrEP coverage in 2019.

Still, many coverage gaps need to be closed and enforcement of existing policy needs to be stepped up to ensure all the people who need PrEP get access to it, experts said.

'I feel like at some level, we have dealt with the policies to the extent that we can. Now it comes to enforcement,' said Jeffrey Crowley, Program Director, Infectious Diseases Initiative at the O'Neill Institute for National and Global Health Law at Georgetown University Law Center.

The Center for Medicare and Medicaid Services declined comment on whether it intended to step up enforcement of its policy as complaints increase over coverage denial.

Some states like California, New York and Colorado have additional rules and policies PrEP drugs. Coverage access in these states and those that have expanded Medicaid is generally better than in the rest of the country, experts said.

'There's policy, and then there's implementing policy— because we have so many different payers and jurisdictions, there's an issue in terms of compliance,' said Kirk Grisham, associate at the Infectious Diseases Initiative at O'Neill Institute, Georgetown University.

Black and Hispanic/Latino people account for most people for whom PrEP is recommended. However, they have the lowest rates of PrEP use among all racial/ethnic groups, according to the CDC. Data from 2020 shows only 9 percent of the nearly 469,000 Black people who could benefit from PrEP received a prescription in 2020, and only 16 percent of the nearly 313,000 Hispanic/Latino people who could benefit from PrEP received coverage.

PrEP coverage is also nearly three times as high in 2020 among males as among females.

U.S. Plans to Extend COVID Emergency; Biden Faces New Challenges to Expanded Health Coverage

(Regulatory Intelligence) - U.S. health officials have confirmed at least one more extension for the COVID-19 public health emergency, temporarily preventing the loss of health coverage for about 15 million people, at a time when a divided Congress leaves the Biden administration with fewer tools to increase access to health insurance. [FN15]

The public health emergency requires states to keep people continuously enrolled in the federal government-aided Medicaid program for low-income individuals and families, without eligibility or verification checks. The provision aimed to ensure a broader group of people had access to treatment for COVID-19, potentially restricting the spread of the virus while reducing medical debt from related health complications.

The Department of Health and Human Services (HHS) last Friday allowed a deadline to provide a 60-day notice to states to end the current emergency declaration to lapse, signaling the forthcoming extension. The threat of a winter surge in COVID cases and the need for more time to transition from the public health emergency to a private health insurance market led to the decision, an official told Reuters.

An additional extension of the emergency would keep the declaration's provisions in place until about mid-April 2023. The emergency has been renewed 11 times in 90-day increments since it began on Jan. 31, 2020. Some healthcare providers had asked the administration to keep the emergency in place beyond January to allow institutions, especially nursing homes and states, to avoid jeopardizing care for vulnerable parts of the population.

Public health experts have sounded caution over a ‘triple threat’ from newer Omicron variants, a resurgent influenza virus and a sharp spike in pediatric hospitalizations caused by an unusually severe respiratory syncytial virus (RSV) in recent weeks.

Divided Congress limits administrations' tools to stem coverage losses

The evolving threat comes as the Biden administration is faced with a divided Congress after it became clear on Tuesday that Democrats were on the verge of losing control over the House of Representatives to Republicans. Some Republicans have already opposed the extension of the health emergency, citing redundant costs at a time when the threat from COVID seemed to have abated.

The administration this week threatened the President would veto a bill from Republican Senator Roger Marshall to terminate the COVID-related emergency if Congress passed it.

'Preserving our ability to respond is more important than ever as we head into the winter, when respiratory illnesses such as COVID-19 typically spread more easily,” a statement from the White House's Office of Management and Budget said. ‘Action by Congress to end these authorities abruptly and prematurely would be a reckless and costly mistake.”

While the administration may still have the authority to block legislation it opposes, there remains little possibility of enacting a legislative solution to accommodate the millions who would lose coverage when the health emergency eventually ends.

About 8.2 million are expected to leave the Medicaid program ? typically for individuals and families below the federal poverty line ? due to loss of eligibility, but another 6.8 million will likely lose coverage due to ‘administrative churn” despite still being eligible, an HHS report estimated. Medicaid is jointly funded by states and the federal government. It is administered by states in accordance with federal standards.

Health officials previously indicated they were preparing for the health insurance marketplace under the Affordable Care Act to play an outsized role in extending premium subsidies to those losing coverage from the Medicaid program. However, only 2.7 million of those likely to lose eligibility may qualify for the ACA's tax credits for premiums, the HHS report indicated.

The Medicaid expansion program ? which allows people with incomes up to 138 percent of the poverty line to enroll in Medicaid and receives about 90 percent funding from the federal government ? could be another key tool to mitigating coverage loss at the end of the PHE, but several states are yet to adopt it over political objections.

Medicaid expansion has been successful when put to a public vote in ballot initiatives -- most recently in South Dakota. However, the remaining 11 state holdouts lack ballot-initiative provisions, leaving the administration with little scope to get the program adopted in more states. An estimated 2 million people would be eligible for Medicaid coverage if these states were to adopt the expansion program.

New Enrollments Surge in ACA Health Insurance Plans for 2023

(Regulatory Intelligence) - Nearly 3.4 million people have so far signed up for coverage in 2023 on the Affordable Care Act's healthcare exchanges across the United States, with new enrollments surging 40 percent over last year's pace, the Department of Health and Human Services said on Tuesday. [FN16]

The higher rate in new sign-ups provides support to the Biden administration's aim to keep the rate of uninsured low, even as an estimated 15 million people are expected to lose health insurance at the eventual end of the COVID-19 public health emergency, which requires states to keep all low and middle-income people enrolled in Medicaid without eligibility checks.

New sign-ups on the healthcare marketplace reached 493,216, as of Nov. 16, compared to 354,137 on the same date last year, the HHS said. At the end of the last week, new enrollments surged to nearly 655,000 people.

Overall enrollment rose 17 percent in the current open enrollment season scheduled to last until Dec. 15. About four out of five people seeking coverage on healthcare.gov are eligible for plans that cost $10 or less due to premiums subsidies and tax credits made permanent in the Inflation Reduction Act, the Biden administration said.

'We are off to a strong start - and we will not rest until we can connect everyone possible to health care coverage this enrollment season,” HHS Secretary Xavier Becerra said.

'We are off to a strong start - and we will not rest until we can connect everyone possible to health care coverage this enrollment season,” HHS Secretary Xavier Becerra said.

Transferring those losing coverage at the end of the emergency to the ACA market remains a key tool for the administration to ensure people have access to health insurance in the absence of employer-sponsored coverage. The emergency is currently in effect till Jan. 11 and will be extended at least one more time, but is expected to be terminated sometime in 2023.

'We have seen an increase in plan selections and a significant increase in the number of new enrollees over the previous year," said CMS Administrator Chiquita Brooks-LaSure. ' 'I am pleased to see such a strong early showing.

Still, the rate of uninsured in the United States ? currently at an all-time low of 8 percent ? is expected to rise dramatically in the coming year as a result of verification checks resuming on state Medicaid programs, more layoffs being announced by companies and a general decrease in interest in health insurance as COVID-19's newer variants cause fewer hospitalizations.

II. MERGERS & ACQUISITIONS

U.S. Sues to Block UnitedHealth's $8 billion Deal for Change Healthcare

(Reuters) - The U.S. Justice Department on Thursday sued to stop UnitedHealth Group's $8 billion acquisition of Change Healthcare, saying the deal would give the largest U.S. health insurer access to its competitors' data and ultimately push up healthcare costs. [FN17]

UnitedHealth announced the all-cash deal in January 2021, saying it would help streamline administrative and payment processes.

UnitedHealth and Change Healthcare offer competing software for processing healthcare claims and together serve 38 of the top-40 health insurers in the country, the Justice Department said in the complaint. They would have at least 75% of that market, it said.

The Justice Department said UnitedHealth knew that access to claims would give it a view into rival health plans at Humana Inc, Anthem Inc, CVS Health Corp's Aetna and Cigna Corp.

'Unless the deal is blocked, United stands to see and potentially use its health insurance rivals' competitively sensitive information for its own business purposes and control these competitors' access to innovations in vital healthcare technology,' Principal Deputy Assistant Attorney General Doha Mekki of the Justice Department's Antitrust Division said in a statement.

UnitedHealth said it would fight the lawsuit.

'The Department's deeply flawed position is based on highly speculative theories that do not reflect the realities of the healthcare system. We will defend our case vigorously,' it said in a statement.

The lawsuit is a continuation of a tougher approach to antitrust by the Biden administration, which has killed a planned deal by Aon Plc and Willis Towers Watson Plc , and Lockheed Martin's plan to buy engine maker Aerojet Rocketdyne.

Healthcare was among the markets listed as an antitrust priority in a White House executive order issued last summer.

The tougher stance casts a shadow on several other recently struck multibillion-dollar deals.

Citi analyst Daniel Grosslight said the companies are unlikely to want to take part in a protracted lawsuit for an asset Citi views as 'nice to have' for UnitedHealth.

Change Healthcare's shares rose about 3% to $20.84, below United's Jan. 5, 2021 offer price of $25.75 per share. UnitedHealth closed off less than 1% to $455.89.

The Justice Department said the deal would give UnitedHealth access to large amounts of sensitive information from its rivals. It said in the complaint, which was filed in the U.S. District Court for the District of Columbia, that it would impact cost of health insurance by employers and their employees.

The case was assigned to Judge Carl Nichols, a former clerk to Supreme Court Justice Clarence Thomas. Nichols was nominated to the court by President Donald Trump.

Seth Bloom, a veteran of the Justice Department now in private practice, called the filing 'a strong and non-frivolous complaint.'

Representative David Cicilline, a Democrat and advocate of tougher antitrust enforcement, said he was 'glad to see' the Justice Department challenge the deal, which he said would 'raise healthcare costs and expand a corporate giant.'

An official with United's Optum business, which would absorb Change if the deal goes through, told Reuters it has for years had access to and safeguarded the very same information that the Justice Department is concerned about. UnitedHealth has not had access to this information, the official said.

The American Hospital Association has been critical of the deal, arguing that combining healthcare data from Change with UnitedHealth's Optum would reduce competition for the sale of healthcare information technology services for hospitals.

Other critics have included the American Medical Association and two groups of independent pharmacists.

Federal Judge Sets Aug 1 Trial Date for Government Challenge of UnitedHealth Deal

(Reuters) - The federal judge hearing the Justice Department's fight to block UnitedHealth Group's $8 billion deal to buy Change Healthcare said on Thursday that the trial would start on August 1. [FN18]

The Justice Department filed a lawsuit to ask a judge to stop the deal in February, saying it would give the largest U.S. health insurer access to its competitors' data and ultimately push up healthcare costs.

Judge Carl Nichols, who was nominated by then-President Donald Trump, said that the trial would last 12 days with the Justice Department allotted seven days and the companies five.

The companies had asked for the trial to start around June 20 while the government had suggested August 24.

In their answer to the government's complaint, UnitedHealth and Change said that one of concerns that the government had about the deal would be moot because they planned to sell Change's claims editing business, which they advertise as a way to ‘improve payment accuracy, reduce appeals, and reap both medical and administrative savings.’

The companies said that they would fight the government on the other harm allegedly caused by the merger. The government had said that UnitedHealth could misuse data from Change's network and hoard innovations so as to better compete in selling health insurance to big corporations.

'Plaintiffs' hypothetical speculation about data and innovations ignores stark market realities and is entirely inconsistent with UHG's long history,' the companies said in their answer to the government complaint.

UnitedHealth announced the all-cash deal in January 2021, saying it would help streamline administrative and payment processes.

UnitedHealth and Change Healthcare offer competing software for processing healthcare claims and together serve 38 of the top-40 health insurers in the country, the Justice Department said in the complaint. They would have at least 75% of that market, it said.

III. OTHER REPORTS

Aetna Plans to Grow Affordable Care Act Footprint by at Least 8 More States in 2023

(Regulatory Intelligence) - CVS Health's Aetna is looking to expand its insurance offering in the Affordable Care Act's marketplaces in at least eight more states in 2023 and likely more markets in 2024, regardless of its performance in the coming year, a company official said. [FN19]

Aetna is currently slated to re-enter the individual health care market in eight states in 2022 as it expects to expand its consumer reach through CVS' retail footprint -- across its traditional pharmacies, “MinuteClinics' akin to urgent care centers and “HealthHub' locations that treat chronic conditions and offer wellness services. CVS acquired Aetna in November 2018.

'We pretty much know where we're going to be going in 2023. I think beyond that, I would be very surprised if we did not continue to expand that footprint in 2024,” said Kristen Miranda, Senior Vice President at Aetna's Markets division told Regulatory Intelligence. ‘We should be absolutely in this segment, in this market.”

Miranda said the company is not ready to disclose its targeted states for 2023 as internal plans were yet to be finalized but added it was moving ‘full steam ahead” on its self-made expansion commitment.

The company expects its Obamacare offering to result in at least 100,000 new members in 2022, CVS' Chief Executive Karen Lynch said on the company's third-quarter earnings call in November. Aetna had close to one million members on its commercial plans in the ACA market at the end of 2016, but that number had dropped to 255,000, prior to its decision to exit the marketplace in 2017.

The planned 2023 expansion will likely continue even if the enrollment falls short of the company's internal expectations, largely due to the increased stability in the ACA market and Aetna's new capacity through the merger with CVS, Miranda said.

'We're really in this for the long haul. Our expectation is that, given that local retail community footprint that we've got, we're going to be a pretty attractive option over time. This was never about 2022,” she said.

If the planned expansion plays out, the insurer will be present in more ACA markets than the 15 states it participated in before its phased exit in 2017-2018. Mounting losses and uncertainty over the future of the Affordable Care Act under former President Donald Trump had sent many insurers out of the marketplace at the time.

The Biden administration has taken steps to expand the scope and reach of the ACA after it survived a challenge in the U.S. Supreme Court. About 95% of consumers in states using the federal ACA exchange are eligible for premium tax credits through the American Rescue Plan Act to lower the cost of their insurance plan, the U.S. Department of Health and Human Services said.

Nearly 4.6 million people have signed up for coverage on the ACA marketplace through the federal and state exchanges, the Centers for Medicare and Medicaid said last week.

Miranda said the enrollment number did not yet look ‘heartening,” but added enrollment would likely pick up in the next few weeks. Historically, ACA enrollment has seen an uptick in the last two weeks before the end of the open enrollment period.

Over 30 million people currently have coverage through the ACA's exchanges or state Medicaid expansion programs, run with federal government aid. Consumers typically need to sign up by Dec. 15 to be eligible for coverage at the start of the new year but the Biden administration has extended the open enrollment period until January 15 to allow more consumers to enroll.

OUTLOOK 2022: U.S. Health Insurers Enter Uncharted Territory with Billing Rules, Lingering COVID

(Regulatory Intelligence) - This year is the first in over a decade where health insurers face a stable operating environment without any challenge to the Affordable Care Act. They are, however, in uncharted territory as they face the prospect of COVID-19 becoming endemic and the need to cope with new surprise billing rules that are mired in controversy. [FN20]

Health insurers may also begin to see the cost impact of health problems put off by patients amid the pandemic disruptions, once those disruptions ease. In addition, health insurers are likely to more fully realize the cost of 'long COVID' -- in which the illness continues to affect a patient for several months after initial infection -- and the impact of new COVID variants on long-term patient health.

Issues over COVID testing and coverage persist

Nearly two years into the pandemic, health experts are saying COVID-19 could defeat attempts to eliminate it, and may linger as an endemic disease for the foreseeable future.

For insurers, rapidly evolving new variants of the virus that causes COVID-19 have continually led to confusion over coverage of testing and treatment. Mandates for insurers to cover COVID-19 infection testing have expanded over time, even as authorities have let lapse regulations related to coverage of COVID treatment without out-of-pocket costs.

The Biden administration has mandated that insurers cover at-home tests for COVID-19 up to a maximum of $12 per test without a prescription. Insurers now must cover at least eight at-home tests per individual, per month, but are allowed to offer the tests through a pharmacy of choice. There is no limit on the number of tests insurers will have to cover if ordered by a healthcare provider.

The evolution of more-contagious virus variants, such as Omicron, could continue to fuel unprecedented demand for COVID-19 testing, while insurers will have to rely on federal and local government efforts to prevent price gouging on at-home testing kits.

In case of the emergence of a vaccine-resistant variant, coverage criteria could be broadened to mimic the pre-vaccine part of the pandemic, where health insurers covered most costs related to treatment, said Ashley Ridlon, vice president of health policy at Evolent Health, a consulting firm. 'It's just hard to say what that trajectory will be."

New surprise billing rules, provider hostility

Insurers and health care providers are also facing a new operating environment in which consumers cannot be billed for most 'extra' charges. The No Surprises Act, which took effect with the new year, protects patients from out-of-network bills related to emergency room services and some non-emergency care.

This could bring new challenges for insurers, who had unsuccessfully asked for more time to comply with the rules related to the act Insurers are likely to face increased disputes with healthcare providers, especially over emergency-care rates.

Insurers are also likely to be under scrutiny over the implementation of the act's final rules. A lawsuit by physicians and hospitals cast attention on the dispute resolution process, alleging that the process outlined by the U.S. Department of Health and Human Services unfairly benefits insurers by tying outcomes to insurers' median in-network rate.

Insurers are likely to be under the scanner for any attempts to keep higher-priced providers out of their networks in a bid to keep their median in-network rates low.

Full cost of deferred care, long-COVID may be realized

Patient use of routine and preventive healthcare services has waned with every surge in COVID infection rates since the start of the pandemic. It is unclear if these consumers will return to seeking routine care at pre-pandemic levels in 2022, but missed preventive screenings and health problems made worse by inattention have been projected to raise insurer costs over time.

Preventive care and treatment for cancer-related conditions are especially concerning industry experts. For instance, mammography claims were down about 35 percent in Nov. 2021 compared to Nov. 2019, while biopsy claims were down 44 percent, said Avalere Health, a consulting firm.

In addition, insurers will likely begin to realize the full cost associated with long-COVID. People who experienced mild symptoms during the initial infection are also reporting new health conditions, such as lung and kidney damage, that can require elaborate treatment.

Insurers have also been drawing attention to drug price increases during the pandemic, making treatment of chronic ailments more expensive at a time when a larger section of the population is beginning to require treatment for these conditions.

Telemedicine coverage framework, mental health care inclusion

Telemedicine, which gained enormous popularity and support since the start of the pandemic, could see push-back from some payers and even some regulators, as pandemic-related reimbursements have been called 'unsustainable."

The U.S. Centers for Medicare and Medicaid Services required insurers to reimburse telehealth visits at in-person visit rates for some categories of coverage in mid-2020. Insurers supported the policy and expanded the benefit to all consumers through the year, but then began imposing restrictions in 2021.

With the return to in-person visits becoming safer this year, lawmakers are expected to work on a telehealth coverage framework with clarity on services that qualify, on reimbursement standards and other criteria for coverage.

Coverage of mental health will likely make it to the list of issues regulators and lawmakers will seek to include in telehealth coverage soon. The pandemic has spurred a mental health crisis in the country, with the U.S. Surgeon General warning about its devastating impact on the youth.

The area of mental health also received the most expansion of benefits from an employer perspective, said Tracy Watts, health policy expert at Mercer Health. ‘Mental health parity is very much at the top of mind of our lawmakers and regulators in Washington, DC,” she said.

Alzheimer's Patient Groups Protest U.S. Medicare Coverage Proposal Limiting Use of New Drugs

(Reuters) - Alzheimer's patient groups, disappointed by Medicare's plan to sharply limit coverage of new drugs for the brain-wasting disease, are planning publicity and lobbying campaigns to protest a proposal they say could delay their use for 10 years. [FN21]

'Congress has to know how bad this will be for patients,' said John Dwyer, president of Global Alzheimer's Platform Foundation (GAP) advocacy group.

In a preliminary decision last week, the U.S. Centers for Medicaid and Medicare Services (CMS), which runs the government health plan for people age 65 and older, said it would cover Biogen Inc's already approved Aduhelm, and similar Alzheimer's disease treatments in development, only for patients enrolled in approved clinical trials.

That plan would severely limit the number of patients receiving the treatment, undercutting the Food and Drug Administration's accelerated approval of Aduhelm for patients in the early stages of the memory-robbing condition.

The public disagreement over the drug's use is unusual for the agencies, both part of the U.S. Department of Health and Human Services.

Alzheimer's Association Chief Executive Harry Johns said Medicare's plan ‘usurps FDA's role in drug approvals,’ calling it ‘an unprecedented and terrible draft decision.’

His group, as well as UsAgainstAlzheimer's and GAP - three of the biggest Alzheimer patient organizations - said they plan to fight the decision by appealing to lawmakers, the Biden administration and the U.S. Health Secretary.

The Alzheimer's Association said it is using ‘all avenues of communication’ to make its case.

Biogen is also fighting the decision and in a statement said it is ‘supportive of the community in raising their voices on this important issue of access.’

The Medicare agency could alter its plan before it is finalized in April, but it is unclear what new evidence or facts would cause it to soften its stance.

'There are only two clinical studies ... There isn't any real-world experience to convince CMS,' said James Chambers, a researcher at the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center in Boston. ‘They will receive a lot of outrage as opposed to new information.’

Medicare has opened a 30-day comment period with a final decision due by April 11.

'If the (CMS) decision changes, it will be because of political pressure,' said Raymond James analyst Chris Meekins.

CONTROVERSIAL DECISION

The FDA's June decision was the first approval of an Alzheimer's drug in nearly two decades, but was a controversial one not supported by the agency's outside advisers. It relied on evidence that the drug can reduce amyloid brain plaques, a likely contributor to Alzheimer's, rather than proof that it slows progression of the disease.

Only one of Biogen's two large-scale trials showed that Aduhelm had an impact on cognition.

The three Alzheimer's patient groups said Medicare's plan unfairly penalizes people with the disease - probably because there are so many of them and the cost could be enormous.

Aduhelm's price - cut recently to $28,200 from $56,000 per year - sparked concerns about Medicare's budget since Alzheimer's is an age-related disease and around 85% of people eligible for the drug are in the government plan.

The number of Americans with Alzheimer's is expected to rise to 13 million by 2050 from more than 6 million currently. Biogen has estimated that around 1 million would currently be eligible for Aduhelm.

Other companies, including Biogen partner Eisai Co Ltd and Eli Lilly and Co, also are pursuing accelerated approval from the FDA for similar medications.

'This decision was not about Aduhelm alone. This was a decision about drugs still in trials,' said UsAgainstAlzheimer's chairman George Vradenburg. ‘It is stunning preemption.’

Medicare typically pays for FDA-authorized medications, but by law is required to cover only products and services deemed ‘reasonable and necessary’ for diagnosis or treatment.

Vradenburg said his organization is ‘communicating with Congress and the Biden Administration’ about its dismay.

U.S. Insurers Seek Changes in Coverage Rules for COVID Tests to Curb Price Gouging

(Regulatory Intelligence) - U.S. health insurers have suggested Congress allow insurers to reimburse out-of-network COVID-19 lab tests at their median contracted price for in-network labs, instead of the current requirement to pay the listed cash price, as part of the Biden administration's efforts to curb pandemic-related price gouging. [FN22]

America's Health Insurance Plans, a trade group, said the requirement has led to widespread overcharging by labs for COVID-19 tests, when not in contract with an insurer. A survey conducted by the industry showed out-of-network providers charged more than $185 for more than half of COVID-19 tests, while the average test costs $130.

Data shows that the problem has gotten worse, not better, since the beginning of the pandemic, AHIP said in a statement submitted to a subcommittee of the House Energy and Commerce Committee last week. The subcommittee on Consumer Protection and Commerce is mulling legislation to stop corporate price gouging during the pandemic.

'We recognize that COVID-19 is here to stay,” AHIP said in its statement ‘In order to foster a strong long-term strategy that keeps health costs down, patient protections need to be put in place to stop the widespread price gouging for out-of-network COVID-19 testing.”

Health insurers should be allowed to reimburse out-of-network labs for COVID-19 tests at their median in-network rate, AHIP said. The change will help protect patients from balance billing, or bills sent by providers to consumers to pay for the remainder of a bill partly reimbursed by an insurer, and rising health insurance premiums that factor in these higher costs.

The requirement for health insurers to cover COVID-19 lab tests in and out of network was laid down by the Coronavirus Aid, Relief, and Economic Security (CARES) Act passed in March 2020.

The CARES Act requires insurers to cover tests for the sake of medical purposes only but insurers are often unable to distinguish between a test taken for diagnostic purposes and screening purposes, such as attendance at work, school or travel, for instance. The Centers for Disease Control and Prevention's (CDC) newly created code, ICD-10, to distinguish diagnostic testing from other screening has not been authorized for use yet. AHIP said Congress could instruct the CDC to allow the use of the ICD-10 COVID-19 screening test code to help make the distinction between medical and non-medical testing and also allow health insurers to implement testing policies consistent with federal coverage and payment policies.

Pennsylvania's Insurance Commissioner to Step Down to Lead California's ACA Marketplace

(Regulatory Intelligence) - Pennsylvania's insurance commissioner Jessica Altman will resign from her position as head of the state's insurance department later this month to lead California's state insurance marketplace, Covered California. [FN23]

One of the youngest state insurance regulators in the country, Altman was confirmed as head of Pennsylvania's Insurance Department (PID) in March 2018 - seven months after serving in an acting position in the same role.

'Commissioner Altman has been a steadfast leader for Pennsylvanians throughout her tenure in state government including protecting access to high-quality, affordable health care by holding insurance companies accountable— and overseeing the creation of the commonwealth's very own state-based exchange, Pennie,” Pennsylvania's Governor Tom Wolf said in a statement.

Altman will resign from her position as insurance commissioner of the nation's fifth-largest insurance market on Feb. 25, according to Wolf. Following her departure, PID's current Chief of Staff Mike Humphreys will serve as Acting Insurance Commissioner of the department, Wolf added.

Prior to the PID, Altman also held positions at a division of the U.S. Department of Health and Human Services Department where she developed policy and facilitated the implementation of the Affordable Care Act.

Altman will join Covered California on March 7, at a time when enrollment on the state's marketplace has hit an all-time high of 1.8 million people, buoyed by the healthcare subsidies in President Joe Biden's coronavirus relief package, the American Rescue Plan.

She said was ‘eager to return home’ and build on Covered California achievements over the last decade.

U.S. Health Insurer Anthem Plans to Rebrand as Elevance Health

(Reuters) - Anthem Inc said on Thursday it intends to change its name to Elevance Health Inc, as the company looks to shift its focus beyond the health insurance business. [FN24]

The U.S. health insurer's rebranding move is not its first, having previously changed its identity from WellPoint Inc around eight years ago.

The rebranding is a first step in the company's effort to optimize its brand portfolio, the insurer said in a statement. Anthem's Blue Cross Blue Shield health plans will not be renamed, it added.

The company, which operates Blue Cross Blue Shield plans in several states, has been attempting to compete in a changing health insurance landscape following deals by rivals such Cigna Corp to merge with the biggest U.S. pharmacy benefits managers (PBMs).

Anthem launched its in-house pharmacy benefits management business, IngenioRx, in 2019 after ending a long-standing deal with Express Scripts Holding Co, which is now a part of Cigna.

In the quarter ended Dec. 31, IngenioRx brought in about 19% of Anthem's total operating revenue.

The company acquired myNEXUS Inc, a home-based nursing management company, in April.

McKesson Loses Bid to Make Insurers Cover Opioid Defense

(Reuters) - Two insurers do not have to cover McKesson Corp's defense costs in lawsuits accusing the drug distributor of enabling rampant illegal opioid sales, a federal judge has ruled. [FN25]

U.S. District Judge Jacqueline Scott Corley in San Francisco on Tuesday ruled that AIG unit National Union Fire Insurance Co of Pittsburgh and ACE Property and Casualty Insurance Co were off the hook because the lawsuits accused McKesson of deliberate conduct, which was not covered by the policies at issue.

Lawyers for McKesson and the insurers did not immediately respond to requests for comment.

More than 3,300 lawsuits have been filed against drugmakers, distributors and pharmacies over the opioid epidemic, which led to nearly 500,000 overdose deaths between 2009 and 2019, according to the Centers for Disease Control and Prevention. Insurers have been reluctant to cover defense costs, sparking court battles over the scope of their policies.

McKesson has agreed to pay $8 billion as part of a $26 billion nationwide settlement finalized earlier this year, which also includes two other distributors and Johnson & Johnson.

The company has said it has spent more than $270 million defending opioid lawsuits in court and has sought coverage of its legal costs from its insurers.

In October 2020, National Union sued the distributor for a declaratory judgment that it was not obligated to cover those defense costs. McKesson in turn sued National Union and ACE, seeking to compel them to pay.

The parties agreed to focus on three ‘exemplar’ lawsuits, brought by Ohio's Cuyahoga and Summit counties and by the state of Oklahoma. McKesson settled with the Ohio counties before trial in 2019, agreeing with two other distributors to pay a combined $215 million, while the Oklahoma case is still pending.

The insurers argued that their policies did not apply because they covered lawsuits over ‘bodily injury’ stemming from an ‘accident.’ They said the opioid lawsuits did not allege bodily injury, instead seeking economic damages on behalf of governments, and that McKesson's alleged conduct was not accidental.

Corley rejected the insurers' argument about bodily injury, finding that the lawsuits did stem from injuries suffered by opioid users even though they were filed by local and state governments.

However, she agreed the lawsuits ‘are based on allegations that McKesson engaged in deliberate conduct,’ since they accuse the company of knowingly failing to guard against the illegal diversion of opioids.

The case is AIU Insurance Co v. McKesson Corp, U.S. District Court for the Northern District of California, No. 20-7469.

U.S. Health Agency Issues Guidance for No Surprises Act Billing Disputes

(Regulatory Intelligence) - The Center for Medicare and Medicaid Services (CMS) has issued updated guidance for its independent dispute resolution process under the No Surprises Act. [FN26]

The update was necessary after a Texas federal court invalidated portions of an interim final rule on February 23, 2022. The Texas Medical Association sued the Biden administration in October 2021 over the dispute resolution process. The court found the agency's rules violated the Administrative Procedure Act by deviating from the statutory language to give more weight to the qualifying payment amount over other factors.

The challenged interim final rule, Requirements Related to Surprise Billing: Part II, established the federal independent dispute resolution process to determine out-of-network payment amounts between providers or facilities and health plans. The dispute resolution process is the next stage following an unsuccessful open negotiation between the parties.

Under the original interim rule, there was a rebuttable presumption that the qualifying payment amount was the appropriate payment for services unless there was convincing evidence to defeat the presumption. A qualifying payment amount is the ‘median of the contracted rates' the insurer would pay an in-network provider for the same or similar service.

Under the updated guidance arbiters will be able to consider more than the insurer's median in-network rates when deciding disputes under the resolution process. Providers will now be allowed to submit other information for the arbiter to consider, including:

• The level of training, experience and quality and outcomes measurements of providers or facilities.

• The regional market share held by the provider or facility.

• The acuity of the patient receiving the service or the complexity of the service.

• The teaching status, case mix and scope of services the facility or provider offers.

• Demonstration of good faith efforts, or lack of efforts, the parties made to enter into network agreements.

• The guidance also clarifies that arbiters are not responsible for deciding if median in-network rates are accurate. It also removes the presumption that the median in-network rate is the appropriate qualifying payment amount.

Earlier this month, CMS launched its online arbitration portal for out-of-network providers and insurers to initiate the independent dispute resolution process when the open negotiation fails to resolve the payment dispute.

CMS Issues New Policies to Provide Greater Transparency for Medicare Advantage and Part D Plans

On April 29, CMS issued a final rule for the Medicare Advantage (MA) and Part D prescription drug programs that will improve experiences for dually eligible beneficiaries and provide greater transparency for the MA and Part D programs. The measures set forth in the Contract Year 2023 MA and Part D Policy and Technical Changes final rule build on the agency's strategic pillars to be a responsible steward of public programs, as it continues to expand access to quality, affordable care and advance health equity for people with Medicare and Medicaid.

'The Biden-Harris Administration has remained committed to ensuring equity in health care for all," said CMS Administrator Chiquita Brooks-LaSure. 'This rule improves the health care experience and affordability for millions of people with MA and Part D coverage, including dually eligible individuals, and provides needed support to populations often left behind."

Expanding access to quality, affordable care and coverage is a priority for the Biden-Harris Administration. This rule finalizes provisions to provide more affordable access to care for 53 million Americans enrolled in Medicare health or drug plans. First, Medicare Part D beneficiaries will see reduced out-of-pocket costs for prescription drugs starting in 2024, resulting from a new requirement that Part D plans pass along the price concessions received from pharmacies at the point of sale. Second, the rule clarifies policies to provide beneficiaries enrolled in MA plans uninterrupted access to necessary services during disasters and emergencies, like the COVID-19 pandemic.

Medicare and Medicaid are distinct programs that operate independently, which can sometimes result in fragmented care for the approximately 11 million individuals dually enrolled in Medicare and Medicaid. Dual eligibility is also a predictor of social risk and poor health outcomes. Many dually eligible individuals experience challenges such as housing insecurity and homelessness, food insecurity, lack of access to transportation, and low levels of health literacy.

The final rule will help close health disparities by delivering person-centered integrated care that can lead to better health outcomes for enrollees and improve the operational functions of these programs. The rule also requires all MA special needs plans to annually assess certain social risk factors for their enrollees because identifying social needs is a key step to delivering person-centered care.

Moreover, the rule also strengthens coordination between states and CMS in serving people dually eligible for Medicare and Medicaid. This includes codifying a mechanism through which states can require dual eligible special needs plans to use integrated materials that make it easier for dually eligible individuals to understand the full scope of their Medicare and Medicaid benefits.

Also, in support of the Biden-Harris Administration's commitment to advancing health equity, CMS is reinstating the requirement that MA and Part D plans inform enrollees of the availability of free interpreter services. Plans will be required to include a multi-language insert in all required documents provided to enrollees. In addition, CMS is closing a loophole for dually eligible MA enrollees who have high medical costs that exceed the maximum out-of-pocket limit established by the MA plan. This loophole had resulted in lower payment to providers serving dually eligible MA enrollees than providers serving non-dually eligible MA enrollees.

The rule also promotes sustainability of the Medicare program. CMS is reinstating medical loss ratio reporting requirements and expanding reporting requirements for MA supplemental benefits. This will improve transparency into MA and Part D plans' underlying costs, revenue, and supplemental benefits, which will benefit beneficiaries and taxpayers.

'Fiscal stewardship is a central principle of the work we do every day," said CMS Deputy Administrator and Director of the Center for Medicare Dr. Meena Seshamani. 'As responsible stewards of the program, this rule enables us to learn more about how the Medicare dollar is being spent on certain Medicare Advantage benefits, such as housing, food, and transportation assistance, in order to better understand how we can most effectively support the health and social needs of people with Medicare."

The rule also strengthens CMS' role as a responsible steward of the Medicare program by leveraging its authority to limit MA and Part D plans' ability to expand existing contracts and/or enter into new contracts if they have previously been poor performers. Additionally, CMS is improving application standards and oversight of MA applicants' provider networks to ensure enrollees will have access to a sufficient network of providers before CMS will approve for the first time or allow an existing MA contract to expand. CMS will also protect Medicare beneficiaries by holding plans accountable to detect and prevent the use of confusing or potentially misleading marketing tactics by third-party marketing organizations.

Ruling Limiting Mental Health Benefits Undermines Fight Against Addiction, Three AGs Say

(Reuters) - The attorneys general of Illinois, Connecticut and Rhode Island on Monday called on a federal appeals court to reconsider a decision allowing insurers to limit coverage for mental health and substance abuse treatment, saying the ruling undermines their efforts to combat a nationwide opioid epidemic. [FN27]

A three-judge panel of the 9th U.S. Circuit Court of Appeals ruled in that United Behavioral Health did not have to cover certain mental health and addiction treatment services for tens of thousands of policyholders, allowing the insurer greater leeway to define ‘medically necessary’ treatment.

If allowed to stand, the 9th Circuit's decision will embolden insurers across the nation to cut back on services to opioid addicts, going against a growing medical consensus about the proper treatment for addiction, the attorneys general said at a press conference.

'The worst-case scenario is that more people will die,' Connecticut Attorney General William Tong said. ‘It makes no sense, when facing the worst public health crisis in America, for insurance companies to prioritize profits over people, and to stand in the way of treatment and prevention.’

Tong said that the 9th Circuit's decision would shift costs to states, and imperil states' efforts to expand access to addiction treatment through large settlements with opioid manufacturers and distributors, including Johnson & Johnson and Purdue Pharma LP.

The three attorneys general filed an amicus brief to the 9th Circuit, backing the plaintiffs' bid for en banc review by a panel of 11 judges.

A coalition of healthcare associations, including the American Hospital Association and the American Association for the Treatment of Opioid Dependence, also filed a brief urging en banc review.

United Health Group, which owns UBH, said that it was committed to providing health coverage that matched the terms of its policies and complied with state and federal rules.

The opioid epidemic has caused more than 500,000 overdose deaths over the past two decades, and it has accelerated in recent years, according to the U.S. Centers for Disease Control and Prevention. More than 107,000 people died of drug overdoses in 2021, and about three-quarters of those deaths involved an opioid drug, according to CDC statistics.

Plaintiffs, who represented a nationwide class of policyholders, sued UBH in 2014, accusing it of violating the Employee Retirement Income Security Act by failing to cover mental health and substance abuse services that fell within commonly accepted medical recommendations.

The lower court ruled in the plaintiffs' favor in 2020. But the appeals court reversed, finding that the insurance policies at issue allowed UBH to reject care that was outside the generally accepted standards of care, without requiring the insurer to cover all care that fell within those standards.

The case is Wit v. United Behavioral Health, 9th U.S. Circuit Court of Appeals, No. 20-17363.

Pharma Group Wins Order Striking Down Patient Assistance Rule

(Reuters) - The biggest U.S. drug industry group has won a court order striking down a federal rule meant to ensure that financial assistance offered by drugmakers to patients is not captured by insurers. [FN28]

U.S. District Judge Carl Nichols in Washington, D.C. sided with the Pharmaceutical Research and Manufacturers of America (PhRMA) on Tuesday in finding that the U.S. Department of Health and Human Services overstepped its authority when it passed the rule in 2020.

PhRMA President Stephen Ubl in a statement called the decision ‘a win for patients' and said insurance companies, not drugmakers, were to blame for siphoning away patient assistance funds.

'We will continue to work with policymakers on solutions that make medicines more affordable and lower what Americans pay out of pocket,' he said.

HHS did not immediately respond to a request for comment.

The dispute centers on programs in which drug companies help patients cover their share of the prescription drug costs that they otherwise could not afford.

In recent years, some insurers have established so-called accumulator adjustment programs, in which they do not count assistance toward patients' deductibles and out-of-pocket maximums. Such programs effectively capture some of the assistance for insurers instead of patients.

In response, HHS's Center for Medicare and Medicaid Services (CMS) in December 2020 adopted a rule that would require drugmakers to pay higher rebates to state Medicaid programs unless they ensure that patients are able to keep all financial assistance for themselves.

Drugmakers already have to pay rebates to Medicaid programs in order to reduce costs, based on the ‘best price’ available for a drug on the commercial market. The rule, which was set to take effect in January 2023, would have required drugmakers to factor the effect of accumulator adjustment programs into their best price calculations.

PhRMA sued HHS last May. In January, it asked Nichols to rule in its favor, arguing that the Medicaid statute defines the ‘best price’ as a price offered by drugmakers to health insurers, and does not allow any accounting for insurers capturing patient assistance.

On Tuesday, the judge agreed that the rule ‘stretches the statutory text too thin.’ He also said it raised ‘feasibility concerns,’ since drugmakers do not negotiate with insurers over accumulator adjustment programs and do not necessarily even have complete knowledge about them.

The case is Pharmaceutical Research and Manufacturers of America v. Becerra, U.S. District Court, District of Columbia, No. 1:21-cv-01395.

US Supreme Court's Leaked Draft Ruling on Abortion Spells Compliance Maze for Insurers

(Regulatory Intelligence) - A leaked draft of a U.S. Supreme Court opinion to strike down a women's right to abortion has triggered a wave of new policymaking as states move to tighten or relax restrictions on reproductive rights ahead of the formal court ruling. Changes in state abortion laws will likely complicate an already intricate labyrinth of women's reproductive health issues for health insurers, including cover for miscarriage and abortion pills. [FN29]

If the Supreme Court formally overturns the landmark 1973 Roe v. Wade decision that legalized the right to abortion in the country, along the lines of the draft opinion from Justice Samuel Alito, ‘trigger laws' already on the books would ban all or nearly all abortions in about 13 states, according to data from the Guttmacher Institute, an abortion-rights advocacy research group. The states include Texas, Oklahoma and Mississippi.

About 16 states and the District of Columbia have laws that protect the right to abortion. Some of these states are taking steps to further codify existing abortion rights while some states such as New York are trying to ease access to abortion for women from other states through grant programs.

In addition, Democrats in Congress are seeking to pass legislation to relax restrictions countrywide. One such attempt on Wednesday was defeated in the U.S. Senate amid strong Republican opposition, but President Joe Biden is said to be considering executive orders to increase access to abortion.

The rapid pace at which state, if not federal, policy is likely to change could trigger compliance problems for insurers. It could also lead to erroneous denials, health emergencies related to abortion delays and further-reduced access to coverage for care that is already hard to find across the United States, experts said.

'It's going to be a compliance issue - no question about it,” said Sara Rosenbaum, professor and health policy expert at Milken Institute School of Public Health, George Washington University. ‘There is also this problem of—whether the states that attempt to shut down abortion will let it be known that they intend to enforce their prohibitions against any insurer that finances abortion,” she added.

States like Texas and Oklahoma have not only restricted abortions but also attempted to criminalize those who aid or abet abortion services. Some bans include vigilante-style citizen enforcement provisions, leaving insurers and employers providing coverage vulnerable to legal action on several fronts.

Restrictions on abortion rights could also strain the existing scant network of abortion providers, leading to the limited coverage of care accessed at an out-of-network clinic and putting patients on the financial hook for some or all of the cost of services. If traveling out of state for abortion becomes more common, consumers may have to solely rely on out-of-network providers to access medical services.

'Health plans in the states where they can cover abortion should expand their networks and welcome as many providers as possible,” said Fabiola Carri?n, director of reproductive and sexual health at the National Health Law Program, an advocacy organization.

About 11 states have prohibited all comprehensive health plans from covering abortion ? except in limited circumstances such as health, rape or incest. Fifteen states prevent plans from covering abortion in health insurance markets, according to the ACLU.

Health advocates worry tightening abortion restrictions may lead to healthcare providers delaying abortions even in cases where a woman's health is at stake or in cases of ectopic pregnancies and miscarriages for fear of noncompliance with official policy.

Growing role for telehealth in reproductive care

The Biden administration and women's rights advocates are preparing to fight these growing restrictions by increasing access to contraceptives and medication abortion pills, especially through telehealth programs.

The U.S. Department of Health and Human Services (HHS) set aside $16.3 million in grant funding to support telehealth infrastructure and federal Title X family planning program clinics in at least 26 states. The HHS has used funding from the COVID-relief American Rescue Plan (ARP) Act to award these grants for a 12-month project period starting May 15, 2022.

Since insurance covers telehealth, health advocates hope women living in states prohibiting abortions will be able to obtain the care they need from in-network medical providers in other states that allow abortion. Providers in these states could mail in the abortion pill to the patient, allowing for access and coverage for the treatment, Carri?n said.

Advocates are also working on ensuring the Centers for Medicare and Medicaid Services also updates its policy and guidance to reflect a new FDA policy that has lifted restrictions on access to abortion pills by mail since December 2021.

Studies conclude that Medicaid recipients and low-income individuals like telehealth because it is more convenient, needs less access to transportation and allows patients to seek care without needing to worry about paying for childcare or missing work, Carri?n said. ‘It's

a very promising rearm and we want to make sure that insurance is really aligned with those flexibilities now, both in the private and public space," she added.

Even as the overall number of abortions has declined across the country, the use of the medication abortion pills mifepristone and misoprostol has increased 73 percent between 2008 and 2017, according to Guttmacher Institute. Medication abortion can cost up to $750 and varies by state, according to Planned Parenthood.

Adding to existing health coverage scarcity

Coverage of reproductive services has always been a tricky area for insurers as polarized political views have driven complicated policies on their coverage. Even in states where abortion is permitted, women have to often go through a state-mandated waiting period or counseling to access medical services. In addition, many states have very few abortion services providers. About five states, Mississippi, Missouri, North Dakota, South Dakota and West Virginia, have only one remaining abortion provider.

Experts said the tightening restrictions on policies could leave insurers and employers less inclined to provide abortion coverage, especially if the law does not require them to, further jeopardizing access to care for women who need abortions. 'It's already a problem for them," said Rosenbaum. 'All we can do is wait for the final decision. Although the leaked draft certainly tells us what we have to brace for, I think it's very hard to start doing business planning right now," she added.

Insurers Warn of Higher Healthcare Premiums from Surprise-bill Rule

(Regulatory Intelligence) - The Biden administration's final rule on how insurers and providers must resolve disputes over bills that cannot be charged to consumers has drawn criticism from insurers and employer groups, saying it could result in higher healthcare costs and insurance premiums to consumers. [FN30]

The final rule from the U.S. Departments of Labor, Health and Human Services, and the Treasury was adopted last week. It implements part of the "No Surprises Act' that went into effect at the start of the year. The act bans 'surprise" and 'balance" bills to patients for medical expenses not covered by their insurer. It requires providers and insurers to instead resolve billing disputes mutually or through an independent arbiter.

The concerns were raised after the administration in its final rule removed an emphasis on arbiters taking the offer closest to insurers' median in-network prices in the independent dispute resolution (IDR) process to settle payment disputes.

The final rule now says arbiters are to take into account the median in-network payment rate but they will also be allowed to consider other factors, such as the provider's training and experience, quality and outcomes, the market share of the provider and insurer in a geographic region and the demonstration of 'good faith efforts" made by the provider and insurer to enter into network agreements with each other.

Healthcare providers successfully challenged the dependence on in-network median rates in the prior version of the rule, saying it would unfairly benefit insurers who could control the final payout by selectively contracting with providers to keep the median in-network rate low. The American Hospital Association declined comment on the final rule.

AHIP, a trade group of health insurers, said it was concerned that providers could use the new rules to 'game the system' of the independent dispute resolution process. Insurers have previously expressed concern about having to pay high costs of providers who do not agree to contracted prices of a service.

'Abusive, provider-initiated arbitration will only blunt the impact of the No Surprises Act, raising health care prices for millions of hard working Americans. We are hopeful the rules will be implemented in a way that discourages unnecessary use of costly arbitration," AHIP said via email on Tuesday.

The ERISA Industry Committee, an advocacy group for employers providing insurance benefits, also said the removal of the emphasis on the final settlement being close to the median in-network price would water down the benefits of the surprise billing rule, by forcing employers to pay 'inflated amounts to out-of-network providers that charge unreasonable fees." 'The administration's actions will not lower health care costs. To the contrary, plan sponsors and the employees they provide health coverage to will continue to be forced to line the pockets of medical providers that choose to remain out-of-network," said Annette Guarisco Fildes, CEO, of the committee.

U.S. Agencies Seek Input on Healthcare No Surprises Act Billing Requirements

(Regulatory Intelligence) - U.S. regulators are requesting public comment on how they should develop healthcare billing requirements for advanced explanations of benefits and good faith estimates under the No Surprises Act. The requirements were enacted under the Consolidated Appropriations Act, 2021. [FN31]

The Office of Personnel Management, Internal Revenue Service, Department of Labor and the Centers for Medicare & Medicaid Services jointly issued the request for information on Friday, with a response deadline of November 15.

The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under the circumstances when most 'surprise' bills arise. Surprise billing occurs when a patient receives an unexpected medical bill from a health care provider or facility, including air ambulance services or out-of-network emergency care.

One provision of the act requires providers and facilities to provide a good-faith estimate of the expected charges for healthcare services. For individuals covered by insurance, the information must be provided to the insurer at the time care or services are scheduled, or at the individual's request . For people without coverage, the good faith estimate must be provided directly to the individual.

The good faith estimate must include the expected charges for the furnished services and any items or services reasonably expected to be provided, including any provided by another provider or facility, along with the expected billing and diagnostic codes for the items or services.

Regulations relating to good faith estimates for uninsured individuals already apply for plan years beginning on or after January 1, 2022.

However, the agencies have deferred enforcement of the regulations relating to good faith estimates for individuals who are insured and would have the claim submitted to their plan or insurer. Implementation was deferred because stakeholders requested that the agencies ‘first establish standards for data transfer’ as well as provide them with ‘enough time to build the infrastructure necessary to support the transfers.’

The agencies are seeking feedback on several issues, including:

• What issues should the agencies consider as they weigh policies to encourage the use of fast healthcare interoperability resources for application programming interfaces (API) for the ‘real-time exchange’ of advanced explanation of benefits and good faith estimates data?

• What privacy concerns does the transfer of advanced explanation of benefits and good faith estimates raise?

• How could updates to the program support the ability of providers and facilities to exchange good faith estimate information and support the exchange of ‘clinical and administrative data, such as electronic prior authorization’?

• Would the availability of certification criteria help to enable interoperability of API technology?

• What burdens or barriers would small, rural or other entities encounter to comply with any adopted requirements?

• Should the agencies consider exceptions or phased-in approaches for small, rural or other entities?

The agencies also solicit comments on other policy considerations that could impact the implementation of the requirements for good faith estimates and advanced explanations of benefits as well as comments on the economic impact of the requirements.

The agencies are continuing to defer enforcement of the requirements for providers and facilities to issue good faith estimates and advanced estimates of benefits for insured individuals until they issue implementing regulations.

The comment request seeks information and recommendations on transferring data from providers and facilities to plans, issuers and carriers as well as the economic impacts of implementing these requirements.

Biden Medicare Costs Victory Due Mostly to Alzheimer's Drug Change

(Reuters) - U.S. President Joe Biden claimed victory on Tuesday for a drop in costs for tens of millions of Americans covered by the Medicare health program, though it is primarily due to a decision to severely limit coverage of an expensive, new Alzheimer's drug. [FN32]

Biden highlighted a drop in premiums next year for the first time in over a decade for Medicare Part B, which among other things covers doctor and hospital visits as well as drugs they administer. He said the result will be a saving of more than $60 a year per beneficiary.

'It's going to be a godsend for many families,' Biden told healthcare advocates in a White House Rose Garden event.

'It's going to take a little while for some of this to kick in, but it's locked in,” he said.

The government Medicare plan covers some 35 million Americans aged 65 and older or who are disabled. Separately, private insurers provide benefits through Medicare Advantage plans to over 29 million people.

Biden portrayed the lower premiums as part of his efforts and those of fellow Democrats in Congress to reduce inflation and healthcare costs for older Americans, a crucial voting bloc ahead of upcoming midterm Congressional elections in November.

The Centers of Medicare and Medicaid Services (CMS), which runs the Medicare health plan, said on Tuesday the bulk of the drop comes from its limiting coverage of Biogen Inc's Alzheimer's drug Aduhelm to patients in clinical trials.

'The 2022 premium included a contingency margin to cover projected Part B spending for a new drug, Aduhelm. Lower-than-projected spending on both Aduhelm and other Part B items and services resulted in much larger reserves,' the agency said.

The standard monthly premium for Medicare Part B enrollees will be $164.90 for 2023, down by $5.20 from 2022, CMS said. The agency had raised 2022 premiums by 14.5%, however, with projected costs for Aduhelm as one of the drivers.

Excluding the drug altogether would have resulted in premiums of $160.30 for 2022, CMS said earlier, meaning the 2023 premiums of 164.90 would have actually represented a 2.8% rise.

Aduhelm was approved over the objections of the Food and Drug Administration's outside advisers, who did not believe data definitively proved the drug's benefit to patients. The Medicare program restricted its coverage, which has led to severely limited use of the Biogen drug.

Biden Administration Announces Lower Premiums for Medicare Advantage and Prescription Drug Plans in 2023

On September 29, the Biden Administration announced that people with Medicare will see lower premiums for Medicare Advantage and Medicare Part D prescription drug plans in 2023. Additionally, thanks to the Inflation Reduction Act, people with Medicare prescription drug coverage will have improved and more affordable benefits, including a $35 cost-sharing limit on a month's supply of each covered insulin product, as well as adult vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP) at no additional cost.

Ahead of the upcoming Medicare Open Enrollment beginning October 15, the Centers for Medicare & Medicaid Services (CMS) is releasing key information, including 2023 premiums and deductibles for Medicare Advantage and Medicare Part D prescription drug plans, to help Medicare enrollees determine the best coverage for their needs.

'Today we're delivering on our commitment to reduce health care costs for Americans, including 64 million people with Medicare," said HHS Secretary Xavier Becerra. 'Thanks to President Biden's Inflation Reduction Act, millions of Medicare enrollees will have lower prescription drug costs and improved benefits when they sign up this year. We will continue working to strengthen Medicare to ensure everyone gets the high-quality, affordable care they deserve."

'The Inflation Reduction Act will provide much needed financial relief and increase access to affordable drugs," said CMS Administrator Chiquita Brooks-LaSure. 'It is more important than ever for people to review their health care coverage and explore their Medicare options during Open Enrollment this year."

Enrollment in Medicare Advantage — private health plans that cover all Medicare Parts A and B benefits and may provide additional benefits — continues to increase. Projections indicate enrollment will reach 31.8 million people in 2023.

The projected average premium for 2023 Medicare Advantage plans is $18 per month, a decline of nearly 8% from the 2022 average premium of $19.52. Medicare Advantage plans will continue to offer a wide range of supplemental benefits in 2023, including eyewear, hearing aids, preventive and comprehensive dental benefits, access to meals (for a limited duration), over-the-counter items, and fitness benefits.

In addition, more than 1,200 Medicare Advantage plans will participate in the CMS Innovation Center's Medicare Advantage Value-Based Insurance Design (VBID) Model in 2023, which tests the effect of customized benefits that are designed to better manage diseases and meet a wide range of health-related social needs, from food insecurity to social isolation. The benefits under this model are projected to be offered to 6 million people.

The VBID Model's Hospice Benefit Component, now in its third year, will also be offered by 119 Medicare Advantage plans in portions of 24 states and U.S. territories, providing enrollees increased access to palliative and integrated hospice care. Medicare Advantage plans participating in the Hospice Benefit Component will implement strategies to advance health equity across all aspects of their participation.

CMS continues to improve options for enrollees who are dually eligible for Medicare and Medicaid. For example, in 2023, CMS will begin to require all Medicare Advantage dual eligible special needs plans (D-SNPs) to establish enrollee advisory committees and consult with those committees on various issues, including improving health equity for underserved populations. Additionally, new policies related to cost sharing are estimated to increase payment from MA plans to providers serving dually eligible individuals who incur high costs.

As previously announced, the average basic monthly premium for standard Part D coverage is projected to be $31.50, compared to $32.08 in 2022. The Medicare Part D program helps people with Medicare pay for both brand-name and generic prescription drugs.

CVS Health, Centene Lead Health Insurers Lower After 2023 Medicare Ratings

(Reuters) - Shares of drugstore operator CVS Health fell as much as 10% and insurer Centene slumped 8%, leading declines in major U.S. health insurers after performance ratings for health insurance plans from a federal government program were released. [FN33]

CVS' largest health insurance plan for Medicare recipients received a lower performance rating, the company said on Thursday, leading to more than $11.6 billion being wiped off its market value by 11:30 a.m. ET on Friday.

The company's shares have fallen more than 13% this year.

Centene, which has fallen more than 10% this year, also lost $3.5 billion of its market value by 11:30 a.m. ET.

Year-over-year declines in Star Ratings were expected due to expiry of the one-time COVID-specific disaster relief program, Oppenheimer analysts said, adding that CVS and Centene were among the biggest decliners.

'CVS will not reduce benefits to offset the impact, meaning the company will fully absorb the 5% margin hit from lost quality bonus payments,' according to J.P. Morgan analysts.

Health insurers UnitedHealth Group, Cigna Corp, Elevance Health, Alignment Healthcare and Humana Inc also fell between 1% and 3%.

The downward shift in Star Ratings will present sector-wide revenue headwind in 2024, Stephens analysts said, adding that a sharp reduction in Centene and CVS members in 4+ Star plans for 2023 will lead to operational hurdles for both the companies.

U.S. Health Agency Aims to Keep up Coverage Levels as ACA Enrollment Begins

(Regulatory Intelligence) - The administration of President Joe Biden is touting low-cost health plans and a slightly wider choice of providers in the Affordable Care Act marketplace as its 2023 open enrollment season began on Tuesday. The success of this enrollment season is also crucial for the administration to preserve the record-low rate of uninsured in the country and ensure fewer people lose coverage when provisions related to COVID-19 public health emergency are likely withdrawn in the coming months. [FN34]

The health emergency, which began in January 2020, has been renewed through the pandemic and is effective until Jan. 11. Health officials will communicate next week on whether it will be extended. Signing up for ACA plans will help millions preserve their coverage even if checks on eligibility, suspended under COVID-19 pandemic measures to increase coverage, are reinstated.

About four out of five people will likely find health plans for less than $10 per month on the marketplace this 2023 enrollment season that will remain open until Jan. 15, the Department of Health and Human Services said.

About 220 insurers will offer plans on the marketplace this year, an increase of 7 from 2022. Insurers offer ACA plans county-by-county; at that level, consumers will on average have about six to seven health plans to choose from, the agency added. About 1% of enrollees will have only one issuer to select, the lowest on the ACA marketplace to date.

'A lot of Americans are looking at prices for some products and are very concerned. But if you want to shop for good health care coverage for yourself and your family — you are going to find that you can actually get yourself quality coverage, real benefits when you really need them," said Xavier Becerra, Secretary of the HHS.

Gains made in 2022's enrollment period helped reduce the rate of uninsured in the United States to an all-time low of 8%, according to data from the National Health Interview Survey. The rate of uninsured had previously clocked a low of 9% in 2016, the data showed.

A record 14.5 million people signed up for coverage on the ACA marketplace in 2022, a 21% jump over the previous year. Enrollment of minority Black and Latino people also grew by about 50 percent last year.

The increase in people getting health coverage is attributed to additional premium subsidies provided by the American Rescue Plan Act, a continuous enrollment provision in Medicaid without eligibility checks during the duration of the public health emergency and some recent state Medicaid expansions. The Biden administration also increased its outreach efforts significantly during every enrollment period.

An additional 1 million people are expected to gain coverage through the change of a rule called the 'family glitch" which prevented families with people with employer coverage from accessing the ACA marketplace for plans at cheaper rates.

The ACA marketplace's benchmark premiums are estimated to increase by an average of 4% across all 50 states and DC, according to KFF, a nonprofit healthcare data provider. The vast majority of enrollees will likely receive a subsidy and therefore be shielded from these increases, KFF added.

Insurers have cited inflationary costs, the labor shortage and the post-pandemic surge in demand for care as the reason for higher premiums in their rate filings.

CVS Looks to 2023 After Opioids Settlement, Medicare Rating Decline

(Reuters) - CVS Health Corp on Wednesday forecast a 2023 profit below Wall Street estimates and said it hoped to mitigate the hit from a performance rating decline for its most popular Medicare plan by encouraging members to shift to other plans. [FN35]

The company also announced it agreed to pay about $5 billion over 10 years to resolve thousands of lawsuits accusing its pharmacy chain of mishandling opioid painkillers. CVS took a pre-tax charge of $5.2 billion in the third quarter related to the settlement, a move that ends years of uncertainty for the company's finances.

CVS' largest health insurance plan for Medicare recipients received a lower performance rating from the U.S. Centers for Medicare and Medicaid Services, which in turn could affect payments from the government for 2024, the company said last month.

CVS said the ratings decline and its loss of Centene's pharmacy benefit management (PBM) contract is expected to reduce 2024 revenue by $2 billion, although that figure could come down with company mitigation strategies.

The diversified healthcare company also disclosed that it is considering selling its Omnicare long-term care business, after last month announcing it will sell its bswift insurance software developer.

The company recorded a $2.5 billion charge related to Omnicare in the quarter.

CVS said it will repurchase shares to meet the 2024 earnings target it set last year, and that it is still open to acquisitions in healthcare services. Lynch described the company as looking for 'the right capabilities at the right time.'

The company earlier this year agreed to buy Signify Health for more than $8 billion.

'At our current valuation, an M&A deal is likely less accretive than share repurchase,' Chief Financial Officer Shawn Guertin said during a conference call.

CVS forecast adjusted 2023 earnings of $8.70 to $8.90 per share, below Wall Street expectations of $9.06, according to Refinitiv data.

'While financial engineering is not the strongest way to meet its previously laid out plans, CVS shareholders will likely appreciate that double-digit earnings growth ... is still possible in 2024 and beyond,' Morningstar analyst Julie Utterback said in a note.

CVS raised its 2022 profit forecast to $8.55 to $8.65 per share from it prior outlook of $8.40 to $8.60 on the strong performance of its health insurance and PBM business.

CVS' health insurance business as well as peers Elevance Health and UnitedHealth have benefited from a slow recovery in elective procedures and a fall in COVID cases that has kept costs in check.

IV. ENFORCEMENT & COMPLIANCE

New York AG Announces $600,000 Data Breach Agreement with EyeMed

(Regulatory Intelligence) - New York Attorney General Letitia James announced a $600,000 agreement with vision benefits firm EyeMed on January 24 that resolves a 2020 data breach involving the personal information of approximately 2.1 million consumers, including nearly 100,000 from New York state. [FN36]

The EyeMed data breach allowed attackers to gain access to an EyeMed email account with sensitive customer information. The compromised information included ‘consumers' names, mailing addresses, Social Security numbers, identification numbers for health and vision insurance accounts, medical diagnoses and conditions, and medical treatment information’ dating back 6 years prior to the attack.

EyeMed provides vision benefits to members of vision plans offered by licensed underwriters and employers.

'New Yorkers should have every assurance that their personal health information will remain private and protected,” said Attorney General James in a release. ‘EyeMed betrayed that trust by failing to keep an eye on its own security system, which in turn compromised the personal information of millions of individuals.’

Background on breach

In June 2020, the attacker gained access to an EyeMed email account that EyeMed clients used to provider sensitive consumer data in connection with ‘vision benefits enrollment and coverage.’ The intrusion lasted approximately a week and allowed the attacker to view emails and attachments including sensitive consumer data dating back 6 years.

In July 2020, the attacker sent approximately 2,000 phishing emails from the compromised email account to EyeMed clients attempting to get login credentials for their accounts. EyeMed's IT department blocked the attacker's access to its system after it noticed the phishing emails and received customer queries. EyeMed then began to investigate the intrusion.

In September 2020, EyeMed began notifying affected consumers whose ‘personal information was compromised during the breach.’ It also offered those customers identity theft protection services.

However, the New York Attorney General determined that EyeMed had ‘failed to implement multifactor authentication’ for the email account even though it was accessible via a web browser and contained a large amount of sensitive personal information. EyeMed also failed to maintain adequate logging of its email accounts, which made the investigation difficult.

Agreement with EyeMed

Under the agreement, EyeMed is required to take measures to protect consumers' personal information from future cyberattacks, including:

• Maintain a comprehensive information security program that keeps paces with technology changes and security threats as well as reporting any security risks to the company's leadership.

• Maintain reasonable account management and authentication, including the use of multi-factor authentication for all administrative or remove access accounts.

• Encrypt sensitive consumer information that it collects, stores, transmits and/or maintains.

• Conduct a reasonable penetration testing program designed to identify, assess and remediate security vulnerabilities in the EyeMed network.

• Implement and maintain appropriate logging and monitoring of network activity that are accessible for a period of at least 90 days and stored for at least one year from the date the activity was logged.

Permanently delete consumers' personal information when there is no reasonable business or legal purpose to retain it.

EyeMed also agreed to pay the state of New York $600,000 in penalties.

Georgia Insurance Commissioner Fines Anthem BCBS $5 million

(Regulatory Intelligence) - The Georgia insurance regulator on Tuesday said it had fined Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. $5 million following a months-long examination into alleged violations of state laws and agency regulations regarding claims settlements and payments. The market-conduct examination covered the period of January 1, 2015, to September 30, 2021. [FN37]

The examination was focused on the plan's internal controls related to the implementation of a provider database system during 2015, implementation of a replacement provider database system during 2021 and the reporting of claims payment data to the department.

'This examination uncovered a number of serious issues, including improper claims settlement practices, violations of the Prompt Pay Act, failure to reply to consumer complaints in a timely manner, inaccurate provider directories, and significant delays in loading provider contracts," Insurance and Safety Fire Commissioner John King said in a statement. 'As a result, our office has issued the largest fine in agency history, with potential additional penalties if certain benchmarks are not reached."

The examination found that provider complaints about the provider database system increased 'noticeably' during calendar years 2015-2018. Many complaints involved processing errors where claims from in-network providers were processed as out-of-network and claims were rejected for 'unknown reasons.'

As a result of the provider complaints, the plan implemented a 'four-phase remediation plan to address provider complaints and claims processing errors' as well as various corrective measures deployed between 2015-2020. Ultimately, the plan implemented a replacement provider database system in April 2021. However, the plan 'continued to experience processing errors that resulted from the implementation of the old provider database system.'

The department determined based on its examination that the plan was out of compliance with the claims-timeliness requirements for several quarters during the period from 2018 to 2021.

The department fined Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. $5 million, mandated a corrective action plan and required Blue Cross Blue Shield to submit a monthly report demonstrating its compliance with the corrective action plan. Failure to adhere to the corrective action plan could result in additional penalties and sanctions.

Blue Cross and Blue Shield of Georgia, Inc. in 2019 merged with and into Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. in 2019. The merged company, Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. is owned and controlled by Anthem, Inc.

U.S. Medicare Advantage Organizations Wrongly Denied Necessary Care - HHS Report

(Regulatory Intelligence) - Medicare Advantage organizations improperly denied prior authorization and payment requests that met Medicare coverage rules, the U.S. Department of Health and Human Services said. The organizations, or MAOs, denied coverage using 'clinical criteria' outside the Medicare coverage rules, requesting unnecessary documentation and making manual review and system errors, according to a report by the HHS Office of Inspector General (OIG). [FN38]

Medicare Advantage is an option in the federal Medicare old-age health program and offers Medicare benefits through private-sector insurers. The benefits are typically provided under managed-care plans and typically include prescription drug coverage and other benefits unavailable under the 'original Medicare' program.

The OIG reviewed a sample of denials of prior authorization requests and payment denials issued during a one week period in June 2019 by 15 of the largest Medicare Advantage organizations, which contract with the Medicare program to provide coverage. The 15 selected MAOs 'accounted for nearly 80 percent of beneficiaries enrolled in Medicare Advantage' during the review period.

Enrollment in Medicare Advantage has doubled since 2011, with 26.4 million or 41 percent of beneficiaries covered in 2021. The Congressional Budget Office projects enrollment in Medicare Advantage plans will increase to 51 percent by 2030.

In its review of Medicare Advantage denials, the OIG found that of the prior authorization requests denied by Medicare Advantage organizations, 13% met Medicare coverage rules and would have been approved under 'original Medicare.' The OIG noted MAOs sometimes required unnecessary x-rays prior to approving more advanced imaging. It also found MAOs requested additional documentation even though the OIG determined the existing documentation supported the medical care.

However, the OIG also noted that Centers for Medicare and Medicaid Services (CMS) guidance 'is not sufficiently detailed to determine whether MAOs may deny authorization based on internal MAO clinical criteria that go beyond Medicare coverage rules.'

The OIG also found that of the payment requests MAOs denied, '18 percent met Medicare coverage rules and MAO billing rules.' The erroneous payment denials were frequently caused by 'human error' during claims-processing reviews as well as system processing errors.

An industry group responded that the report found '9 in 10 prior authorization coverage denials were consistent with Medicare coverage rules and more than 8 in 10 denials for payment requests met Medicare billing rules.' The Better Medicare Alliance identifies Aetna, Humana and UnitedHealth Group as 'allies.' They are also among the largest Medicare Advantage plans in the United States.

The OIG found that MAOs reversed some of the denials, often after the beneficiary or their provided appealed or disputed the denial, and in some cases the MAOs identified their own errors.

The OIG report recommends that CMS issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; update CMS audit protocols to address issues identified in its report and direct MAOs to take steps to address vulnerabilities that can lead to manual or system errors.

Supreme Court Turns Away Challenge to U.S. Vaccine Rule for Health Workers

(Reuters) - The U.S. Supreme Court on Monday declined to hear a challenge by Missouri and nine other states - mostly Republican-led - to President Joe Biden's COVID-19 vaccine mandate for workers in healthcare facilities that receive federal funds. [FN39]

The justices turned away an appeal by the states after a lower court declined to immediately consider their claims that the vaccine rule violates federal administrative law and tramples over powers reserved for the states under the U.S. Constitution. The Democratic president's administration issued the rule in November 2021.

The Supreme Court ruled in a 5-4 decision in January to let Biden enforce the healthcare worker mandate while litigation on its legal merits continued in lower courts. The justices at the same time decided 6-3 to halt his administration's rule requiring vaccines or weekly COVID-19 tests for employees at businesses with at least 100 employees.

Biden's administration had argued that the two mandates would save lives and strengthen the U.S. economy by increasing the number of vaccinated Americans. The United States leads the world in COVID-19 deaths, reporting more than a million since the pandemic took hold in the early months of 2020.

The federal healthcare worker rule requires vaccination for about 10.3 million workers at 76,000 healthcare facilities including hospitals and nursing homes that accept money from the Medicare and Medicaid government health insurance programs for elderly, disabled and low-income Americans.

The Supreme Court in January concluded that Biden's regulation fit within the power Congress conferred on the federal government to impose conditions on Medicaid and Medicare funds. It decided that ensuring that medical providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the 'fundamental principle of the medical profession: first, do no harm.'

Missouri sued alongside Nebraska, Alaska, Arkansas, Iowa, Kansas, New Hampshire, North Dakota, South Dakota and Wyoming - winning an injunction against the requirement in those states.

The mandate had also been blocked in 15 other states, including Arizona and Texas, following litigation there.

After the justices in January stayed preliminary injunctions issued by lower courts against the rule, including in Missouri's lawsuit, the state asked the St. Louis-based 8th U.S. Circuit Court of Appeals to expedite hearing the merits of the case.

Biden Takes Action to Lower Health Care and Prescription Drug Costs

On October 14, U.S. President Joe Biden signed an executive order directing the Department of Health and Human Services (HHS) to explore additional actions to lower prescription drug costs.

Beginning this January, seniors and other Medicare beneficiaries will begin to see the benefits of these cost-saving measures. Because of the Inflation Reduction Act:

• A month's supply of insulin will be capped at $35 starting on January 1, 2023.

• Medicare beneficiaries will pay $0 out of pocket for recommended adult vaccines covered by their Part D plan, including the shingles vaccine ? which costs seniors up to $200.

• Prescription drug companies that try to raise their prices faster than inflation will be required to pay Medicare a rebate.

Earlier this year, HHS released a report showing that the price of 1,200 prescription drugs rose faster than inflation in just the last year. For example, one manufacturer of a drug used to treat high blood pressure and heart failure, used by millions of Medicare beneficiaries, increased the drug's price by nearly 540 percent in 2022. Another drug used to treat autoimmune conditions increased by $1000 just this year.

Under the executive order, HHS will have 90 days to submit a formal report outlining any plans to use the Innovation Center's authorities to lower drug costs and promote access to innovative drug therapies for Medicare beneficiaries. This action would build on the Inflation Reduction Act's landmark drug pricing reforms and help provide additional breathing room for American families.

Anthem Must Face U.S. Government Lawsuit Alleging Medicare Advantage Fraud

(Reuters) - A federal judge ordered Anthem Inc to face a U.S. government lawsuit claiming it submitted inaccurate diagnosis data, enabling the health insurer to fraudulently collect tens of millions of dollars in annual overpayments from Medicare. [FN40]

In a decision released on Monday, U.S. District Judge Andrew Carter in Manhattan said the total alleged overpayment to Anthem appeared to be well over $100 million, making the government's financial costs 'substantial and not merely administrative.'

A lawyer for Anthem declined to comment. The Indianapolis-based insurer did not immediately respond to a request for comment.

The Department of Justice lawsuit filed in March 2020 stemmed from Anthem's operation of dozens of Medicare Part C plans, also known as Medicare Advantage, a privatized system that insures Americans who opt out of traditional Medicare.

Anthem was accused of not checking the accuracy of diagnosis codes it submitted when seeking reimbursements between early 2014 and early 2018, because deleting invalid codes would have reduced revenue.

One company executive was quoted in 2016 as saying Anthem viewed its ‘retrospective chart review,’ which supplemented codes it had already collected from doctors, as a ‘cash cow.’

The Justice Department sued Anthem under the federal False Claims Act, which prohibits submitting false payment claims, and sought civil fines and triple damages. Carter's decision is dated Sept. 30.

Anthem's case is one of multiple Justice Department civil lawsuits against companies that participate in Medicare Advantage.

The government watchdog MedPac said excess Medicare Advantage billing linked to what it calls ‘coding intensity’ reached $12 billion in 2020.

Enrollment in Medicare Advantage has doubled since 2013 to about 28.7 million, or approximately 49% of all eligible Medicare beneficiaries, MedPac said in July.

The case is U.S. v. Anthem Inc, U.S. District Court, Southern District of New York, No. 20-02593.

United States Files Civil Fraud Lawsuit Against Cigna For Artificially Inflating Its Medicare Advantage Payments

Damian Williams, the United States Attorney for the Southern District of New York, announced on October 17 that the United States has filed a civil healthcare fraud lawsuit against CIGNA CORPORATION and its subsidiary Medicare Advantage Organizations (collectively, ‘CIGNA”). The lawsuit seeks damages and penalties under the False Claims Act for CIGNA's submissions to the Government of false and invalid patient diagnosis codes to artificially inflate the payments CIGNA received for providing insurance coverage to its Medicare Advantage plan members. The Government is intervening in a lawsuit filed by a whistleblower, which was originally filed in the United States District Court for the Southern District of New York and later transferred to the Middle District of Tennessee.

The Government's complaint alleges that the reported diagnoses codes were based solely on forms completed by vendors retained and paid by CIGNA to conduct in-home assessments of plan members. The healthcare providers (typically nurse practitioners) who conducted these home visits did not perform or order the testing or imaging that would have been necessary to reliably diagnose the serious, complex conditions reported and were prohibited by CIGNA from providing any treatment during the home visit for the medical conditions they purportedly found. The diagnoses at issue were not supported by the information documented on the form completed by the vendor and were not reported to CIGNA by any other healthcare provider who saw the patient during the year in which the home visit occurred. Nevertheless, CIGNA submitted these diagnoses to the Government to claim increased payments and falsely certified on an annual basis that its diagnosis data submissions were ‘accurate, complete, and truthful.”

U.S. Attorney Damian Williams said: ‘As alleged, CIGNA obtained tens of millions of dollars in Medicare funding by submitting to the Government false and invalid diagnoses for its Medicare Advantage plan members. CIGNA knew that, under the Medicare Advantage reimbursement system, it would be paid more if its plan members appeared to be sicker. This Office is dedicated to holding insurers accountable if they seek to manipulate the system and boost their profits by submitting false information to the Government.”

Medicare Advantage, also known as the Medicare Part C program, provides health insurance coverage for tens of millions of Americans who opt out of traditional Medicare. Under Medicare Part C, Medicare Advantage Organizations ('MAOs”), typically operated by private insurers like CIGNA, provide coverage for Medicare beneficiaries. In return, MAOs receive capitated payments from the Centers for Medicare and Medicaid Services ('CMS”) based on demographic information and the diagnoses of each plan beneficiary. MAOs submit diagnosis data, typically passed along from beneficiaries' healthcare providers, to CMS. CMS then uses that diagnosis data, in conjunction with demographic factors, to calculate a ‘risk score” for each beneficiary and, in turn, the amount of the monthly capitated payment that the MAO will receive for covering that beneficiary. The Medicare Advantage payment model is intended to pay MAOs more to provide healthcare for sicker enrollees (expected to incur higher healthcare costs) and less for healthier enrollees (expected to incur lower costs).

The following allegations are based on the Complaint that was filed in federal court:

CIGNA, through its subsidiaries and affiliates, owns and operates numerous MAOs that administer Medicare Advantage Plans. CIGNA contracted with several vendors to conduct home visits of Medicare Advantage plan members across the country as part of its broader so-called '360 comprehensive assessment” program. The home visits were typically conducted by nurse practitioners, and on occasion by other non-physician healthcare providers such as registered nurses and physician assistants (the ‘Vendor HCPs”). Based on the visit, the Vendor HCPs completed a CIGNA-created form ('360 form”) that included a check-the-box multi-page list of a wide range of medical conditions. CIGNA had its coding teams identify diagnosis codes that corresponded to the recorded medical conditions and then submitted those to CMS for risk adjustment payment purposes.

CIGNA structured the 360 home visits for the primary purpose of capturing and recording lucrative diagnosis codes that would significantly increase the monthly capitated payments it received from CMS. The purpose of the visits was not to treat patients' medical conditions, and CIGNA explicitly prohibited the Vendor HCPs from providing actual patient treatment or care. As CIGNA acknowledged

in an internal document discussing the program, '[t]the primary goal of a 360 visit is administrative code capture and not chronic care or acute care management." But this was not disclosed to CIGNA's plan members when the home visit was scheduled or during the actual visit. When identifying plan members to receive home visits, CIGNA targeted individuals who were likely to yield the greatest risk score increases and thus the greatest increased payment.

The Vendor HCPs spent limited time with the patients and did not conduct a comprehensive physical examination. When completing the assessments and recording the diagnoses, the Vendor HCPs relied largely on the patient's own self-assessment and their responses to various basic screening questions. Vendor HCPs did not have access to the patient's full medical history and typically did not obtain or review relevant records from the patient's primary care physician in advance of the visit.

CIGNA's 360 home visit program regularly generated false and invalid diagnosis codes for certain serious, complex conditions that cannot be reliably diagnosed in a home setting and without extensive diagnostic testing or imaging. In tens of thousands of instances, CIGNA submitted diagnosis codes that represent serious, complex medical conditions that (a) were based only on the home visits conducted by the Vendor HCPs; (b) required specific testing or imaging to be reliably diagnosed, which was not performed; (c) were not supported by the information documented on the 360 form completed by the Vendor HCPs; and (d) were not reported by any other healthcare provider who saw the plan member during the year in which the home visit occurred (the 'Invalid Diagnoses"). The Invalid Diagnoses included, but are not limited to, diagnoses for complex medical conditions such as chronic kidney disease, congestive heart failure, rheumatoid arthritis, and diabetes with renal complications. According to CIGNA's own clinical guidelines, accurately diagnosing these conditions requires specialized testing.

CIGNA exerted pressure on Vendor HCPs to record high-value diagnoses that significantly increased risk adjustment payments. CIGNA management identified at least twelve classes of generic chronic diagnoses that they thought were 'often underdiagnosed" among its Plan members and, through trainings and seminars, encouraged the Vendor HCPs to make these diagnoses during the home visits. CIGNA also closely tracked the volume and nature of the diagnoses generated by each vendor's home visits, as well as how the diagnoses affected risk-adjusted payments. CIGNA provided trainings to vendors to improve their 'performance" when they failed to deliver the expected level of high-value diagnosis codes.

Indeed, CIGNA tracked the return on investment of the 360 home visit program by comparing the costs of the in-home visits (i.e., payments to vendors) against the additional Part C payments generated by increased risk scores. For example, according to an internal report, CIGNA determined that, during the first nine months of 2014, one vendor's 6,658 in-home visits resulted in more than an additional $14 million in Medicare payments, which dwarfed the approximately $2.13 million that CIGNA paid to the vendor. When specific providers were found to have captured fewer diagnoses than expected, CIGNA asked the vendor to prepare a 'performance improvement plan" for the provider.

The Invalid Diagnoses generated by the 360 home visits also did not conform with the International Classification of Diseases ('ICD") Office Guidelines for Coding and Reporting (the 'ICD Guidelines"), as required by applicable federal regulations. The Invalid Diagnoses did not affect patient care, treatment, or management during the home visit, as required under the ICD Guidelines, and thus were ineligible for risk adjustment. In addition, the Invalid Diagnoses were not supported by the minimal information recorded on the 360 forms, in violation of the ICD Guidelines' medical record documentation requirement. In fact, in some cases, the 360 forms include clinical exam findings that contradict the supposed diagnosis. For example, one patient received a congestive heart failure diagnosis from a home visit even though the 360 form explicitly noted that physical exam results found her heart to be 'regular" and 'normal" and stated, 'cardiac reviewed and unremarkable."

Through its 360 home visit program, CIGNA submitted diagnosis codes for tens of thousands of Invalid Diagnoses to CMS that constituted false claims for payment. Based on these unlawful false claims, CIGNA improperly received tens of millions of dollars in risk adjustment payments from CMS, in violation of both the False Claims Act and the common law.

[FN2]

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