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IN THE NEWS

Indian-Made Cold Syrup Sent to Iraq Contains Poison, Test Shows

A cold medication made in India and sold in Iraq is tainted with toxic chemicals, a test commissioned by Bloomberg News shows, the latest in a series of alarming revelations about syrup medicines used by children around the world.

A bottle of Cold Out purchased at a pharmacy in Baghdad in March contains 2.1% ethylene glycol, according to Valisure LLC, an independent US laboratory. That's about 21 times the widely accepted limit. The compound is lethal to humans in small amounts and played a role in mass child deaths caused by Indian-made cough syrups in Gambia and Uzbekistan last year. Bloomberg shared the test results with the World Health Organization as well as Iraqi and Indian officials on July 8. The WHO told Bloomberg that it found Valisure's test results to be "acceptable" and that it will issue an alert if the Iraqi government confirms the product was sold there. No public alert or recall has been announced yet. Saif al-Bader, a spokesman for Iraq's health ministry, said in an interview that the ministry has "strict regulations for the import, sale and distribution of medicines." He declined to answer specific questions about Cold Out.

It's the fifth time in a year that testing has found an Indian exporter's drugs to contain excessive levels of ethylene glycol. In addition to the Gambia and Uzbekistan outbreaks, testing by government laboratories has identified other contaminated products in the Marshall Islands and Liberia, although there were no reported illnesses associated with those drugs. The Cold Out label indicates it was made by Fourrts (India) Pvt. Ltd., a Chennai-based manufacturer that exports medicines to more than 50 countries, including the UK, Germany and Canada. A vice president there, Bala Surendran, said that Fourrts subcontracted the manufacture of Cold Out to another Indian company, Puducherry-based Sharun Pharmaceuticals Pvt. Ltd. After Bloomberg's inquiries, Fourrts tested a sample of Cold Out it had on hand and found it untainted, Surendran said. He said Indian regulators seized other samples from Sharun's plant and that Fourrts hasn't been informed of the results of those tests. Officials at the national drug agency and two local regulators either did not respond to requests for comment or said they had no information to share. Sharun executives did not respond to requests for comment.

The outbreak last year in Gambia killed more than 60 children, and the one in Uzbekistan killed about 20. The incidents raised fresh questions about the quality of drug exports from India, which is the largest generic drugmaker and calls itself the "pharmacy of the world." The WHO said this month that a cough syrup blamed for 12 child deaths in Cameroon this year contained unsafe levels of diethylene glycol, a similar toxic compound. In that case, the medicine packaging doesn't name a maker but bears the manufacturing license number of another Indian company. Earlier this year, as part of an investigation into the global trade in unsafe drugs, Bloomberg purchased 33 samples of Indian-made syrups from pharmacies in Cambodia, Georgia, Ghana, India, Iraq and Kenya. The drugs were tested by New Haven, Connecticut-based Valisure using gas chromatography-mass spectrometry. The lab found four samples, all different brands, that contained either ethylene glycol, diethylene glycol, or both.

In considering whether a drug product contains unsafe levels of ethylene glycol or diethylene glycol, the WHO uses a guideline of 0.1%. Levels above that "would be considered non-compliant and therefore a health risk," Rutendo Kuwana, head of the organization's substandard medicines team, said in an email. Sarah Sheppard, a WHO spokeswoman, pointed to guidance from the US Food and Drug Administration that uses the 0.1% limit for tests of raw materials used in syrup production. Valisure tested the Cold Out sample five times and found, on average, ethylene glycol content of 2.1% and diethylene glycol content of 0.25%. The diethylene glycol content is more than twice the limit. None of the other syrups with contaminants exceeded the 0.1% level. Bloomberg provided WHO and Iraqi authorities with test results

and the name and location of the Baghdad pharmacy where the syrup was purchased. The WHO's Sheppard said in an email this week that Iraq continues "to attempt to source samples to confirm (or not) whether the product is in their country and where else it could be on sale. To raise a definitive alert, WHO and the Member State would need to be satisfied that it was on sale in a particular location."

"We will issue an alert as soon as we have confirmation of the information from Iraq," Sheppard continued. Syrup medications consist of a small amount of active ingredient suspended in a watery solution. To cause the active ingredients to dissolve, manufacturers add a solvent such as propylene glycol — a harmless, clear, sweet-tasting liquid. Ethylene glycol and diethylene glycol are chemically similar to propylene glycol but are cheaper and highly toxic, used in industrial applications such as antifreeze and brake fluid. Typically, contamination takes place when a chemical trader mislabels one of these chemicals as propylene glycol. Drug manufacturers are supposed to test propylene glycol for contamination prior to using it, but that doesn't always happen.

In response to the contamination episodes that came to light over the past year, Indian drug authorities in June began requiring the testing of cough syrups in a government lab prior to export. The packaging of the Cold Out obtained in Iraq indicates it was manufactured in January 2022. The WHO has said that it's exploring whether a spike in prices of propylene glycol contributed to the recent contamination cases. In addition to those linked to Indian medication, an outbreak last year in Indonesia, caused by medication manufactured domestically, killed about 200 children. Propylene glycol prices tripled in China in 2020 and in India in 2021 and remained elevated for more than a year, according to ChemAnalyst, a market research firm in India. That increased the potential profit from mislabeling a cheaper solvent as propylene glycol. Valisure is known for finding dangerous chemicals in drugs and personal-care products. Its 2019 research on contamination in the blockbuster heartburn drug Zantac led to recalls and eventual market withdrawal. Valisure works with health-care companies including Kaiser Permanente to test drug products for quality.

Medicare Patients' Health Records Breached in MOVEit Hack

More than 600,000 people in the US Medicare program may have had personal data including medical records exposed through a data breach.

The data was on systems belonging to Maximus Federal Services, a unit of Maximus Inc., that used file transfer software MOVEit, Medicare announced in a statement. A vulnerability in the MOVEit software exploited by hackers has been tied to a widening circle of data breaches at companies and public agencies.

Medicare patients may have had some of their most intimate health information exposed, including medical histories and visit notes, diagnoses, images and treatments, along with names, dates of birth, contact information and insurance data, the agency said.

Maximus alerted the Centers for Medicare and Medicaid Services to the breach on June 2, three days after it detected unusual activity on the MOVEit program, according to the agency. CMS systems were not directly affected, the agency said.

Maximus said in a statement that it's investigating the breach and that other parts of its corporate network were unaffected.

The agency and the company are contacting the 612,000 people affected and intend to offer free credit monitoring services and instructions on how they can replace compromised Medicare cards. The Medicare program covers about 65 million Americans.

Maximus, based in McLean, Virginia, is a large government contractor that gets almost half its revenue from US federal agencies, according to a company filing. The company brought in nearly $2.5 billion in unclassified contract awards from CMS since 2019, according to Bloomberg Government data. A little over $2 billion of that was made up of three call center contracts — the latest set to expire in 2031.

How Drugmakers Can Dodge Medicare Price Negotiations: Explained

Drug manufacturers wishing to avoid negotiating lower prices with the federal government can voluntarily withdraw from the Medicare program—a move that would have a profound impact on market access and coverage of lifesaving therapies for millions of Americans.

The Centers for Medicare & Medicaid Services is approaching a Sept. 1 deadline to publish the list of the first 10 Part D, or prescription, drugs that will face negotiated prices under the Inflation Reduction Act. The law gave Medicare the authority to negotiate lower prices with manufacturers on the drugs it spends the most on.

The Biden administration has promoted the negotiation program as a landmark policy that it says will lower both Medicare spending and Americans' prescription drug costs. But the law faces multiple lawsuits from the pharmaceutical industry. They argue the law forces companies into negotiations and unconstitutionally grants Medicare the authority to ultimately set the prices of pharmaceuticals.

But drugmakers do have a choice: revised agency guidance published in June clarified that companies like Merck & Co. and Bristol-Myers Squibb Co. can decline to participate in the negotiations. If they do, they'd have to withdraw their products from all federal health programs. "Most companies will have strong incentives to remain in the negotiation program so that they do not lose access to these markets for their products," said Stacie Dusetzina, a health policy professor at Vanderbilt University whose specialties include prescription drug costs.

1. What does the withdrawal process look like?

After the CMS announces the first 10 drugs, manufacturers of these products have until Oct. 1 to agree to enter negotiations with Medicare. The negotiated prices would take effect in 2026.

Under the CMS guidance, a manufacturer that wants to end this agreement with Medicare over a particular product must submit a formal request to the agency. If they don't, they risk facing an excise tax. Because the IRA made the drug price negotiations a condition of voluntary participation in the Medicare program, manufacturers looking to end a drug price negotiation agreement must also submit requests to end agreements under the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program, according to the guidance.

This would effectively mean that none of a manufacturer's products—including the drug subject to negotiation and any of the company's other drugs—would be covered by Medicare or Medicaid.

2. When can they withdraw, and how long will it take?

Manufacturers can request to end a negotiation agreement on a selected drug either before or after both parties agree to a maximum fair price, according to the IRA. If a manufacturer meets all the requirements for ending a negotiation agreement, the agency will consider the agreement terminated "on the first date on which the notices of termination for all applicable agreements have been received and none of the drugs of

the Primary Manufacturer are covered by an agreement under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program," according to the guidance.

In termination requests, manufacturers must show they won't form new agreements with any of these federal programs through the end of the year in which a negotiated price would have been applied to their drug.

3. Are any companies considering this?
The pharmaceutical companies with lawsuits against the IRA haven't indicated that they are looking to withdraw from Medicare—and several have noted that doing so wouldn't be in their best interest. aintaining coverage agreements with the federal government means the companies have access to the more than 65 million Americans covered by Medicare and more than 86 million enrolled in Medicaid as of March 2023. Merck said in its complaint that "no rational manufacturer could simply withdraw from half of the U.S. prescription drug market, leaving tens of millions of patients without their medicines." The New Jersey-based drug manufaturer, along with each of the other individual companies challenging the IRA, compared denying access to government health markets to "economic dragooning" amounting to "a gun to the head."

And drugs from several of these companies currently take up a large chunk of Medicare spending. Roughly $47.7 billion, or 22% of total gross Medicare Part D spending, went to the top-10 selling drugs in the program in 2021, according to a KFF analysis. Medicare spent the most—$12.6 billion—on Bristol's anticoagulant medication Eliquis. Other top-selling drugs that year included Janssen Pharmaceuticals Inc.'s Xarelto and Merck's Januvia. Astellas Pharma is one of four drugmakers that have sued the Biden administration in an attempt to halt the drug pricing program. A spokesperson for Astellas said the company is closely monitoring Medicare's implementation of the IRA price-setting provisions. But the company remains steadfast in its position that the price-setting program, as it currently exists, is "unconstitutional." The other three major drugmakers that have filed lawsuits include Merck, Bristol, and Johnson & Johnson. The industry's main trade group, the Pharmaceutical Research and Manufacturers of America, or PhRMA, is also challenging the IRA in court.

The US Chamber of Commerce has asked a federal judge to issue a preliminary injunction halting the negotiations while litigation proceeds. Merck declined to comment. Bristol and Johnson & Johnson didn't respond to multiple requests for comment.

4. How would this affect patients?
Once a manufacturer terminates agreements with Medicare and Medicaid, their drugs would no longer be covered by the agency and the program. Medicare beneficiaries could continue to receive the drugs, but would have to pay for them out-of-pocket.

This could affect patients who rely on drugs like Merck's Keytruda, an immunotherapy that treats at least a dozen cancers and has a list price of more than $150,000 a year. Keytruda is one of the top products analysts predict will be selected for the first round of Medicare price negotiations.

Manufacturers that withdraw from Medicare could offer patients copay coupons to help patients pay for drugs, though it's unclear how far this assistance would go. Federal anti-kickback laws prohibit companies from offering coupons to Medicare beneficiaries for covered drugs.

LEGISLATIVE/REGULATORY

Bill to Overhaul Organ Transplant System Heads to Biden's Desk

President Joe Biden's expected signature will provide the final action needed to give the federal government the authority to break up the monopoly contract used to manage the nation's troubled organ donation system since 1986.

The Senate on Thursday night used a fast-track agreement to pass H.R. 2544, which would allow—for the first time—competitive bidding on multiple contracts to manage the Organ Procurement and Transplantation Network (OPTN), which maintains a national registry to help match organ donors with needy recipients. The legislation, which passed the House by voice vote earlier this week, was adopted by the Senate through unanimous consent, an agreement that sets aside procedural rules when there's no opposition in order to expedite proceedings.

Sens. Chuck Grassley (R-Iowa) and Ron Wyden (D-Ore.) had previously introduced companion legislation, S.1668. The bipartisan H.R. 2544, which was introduced by Reps. Larry Bucshon (R-Ind.), and Robin Kelly (D-Ill.), would enable public and private entities to bid on OPTN contracts. Any new contractors would likely compete to assume many of the responsibilities now handled by the United Network for Organ Sharing, or UNOS, which has managed the OPTN network under federal contract since 1986.

A private nonprofit organization, UNOS has long drawn criticism from patients, lawmakers, and patient advocates. They say the organization has been slow to address technology failures, is unaccountable to patients on the organ waiting list, has allowed too many organs to go unused, and has shown little oversight over the regional organ procurement agencies that solicit and collect donated organs. More than 104,000 people are on a waiting list for a transplant in the US, and 17 die each day waiting for an organ. Another 13 are removed from the waiting list each day because they become too sick for a transplant. The current OPTN contract with UNOS is set to expire Sept. 30, 2023, and will be up for renewal.

Thursday's quick Senate passage follows the July 25voice-vote passage in the House. The legislation will now go to Biden's desk, where it will be warmly received. The president's fiscal year 2024 budget featured legislative proposals to "modernize statutory tools" regarding the OPTN. And in March, the Health Resources and Services Administration of HHS announced a massive "modernization initiative" that included bringing competition to the OPTN contract.

In a statement, Grassley said the legislation is "proof that bipartisanship still works in Washington." "I've been grateful to have support from my colleagues on both sides of the aisle since I first began investigating the organ industry in 2005," Grassley said. "At long last, Congress has succeeded in untangling years of deadly errors in the organ industry to give patients a better shot at lifesaving care and root out corruption."

The Senate Finance Committee began a bipartisan investigation into UNOS in 2020. In August 2022, Grassley and Wyden released a 66-page memo with findings from the investigation. It included numerous allegations of mismanagement and other improprieties by UNOS. At a subcommittee hearing of the Senate Finance Committee on July 20, committee chairman Wyden promised that lawmakers would be "pulling out all the stops to get the Senate to act on this issue as soon as possible," because "this is a matter of life and death for too many Americans."

Under UNOS' watch, the system has been especially harmful to minorities who are disproportionately represented on the organ waiting list but, on average, wait longer for a transplant, and are a higher risk of dying while waiting, Wyden said on the floor of the Senate Thursday. "This is morally repugnant," Wyden said. "And this legislation begins, finally, to root out this bias against our minority communities." "The last place anybody wants to hear about gross mismanagement and incompetence is in the business of saving lives. It's time for real accountability and real change," Wyden said. In June, UNOS announced that it did not oppose the legislation.

In an earlier statement, UNOS said it supported "modernizing and reforming the nation's organ donation and transplant system and working with Congress to achieve measurable results for patients." "As long as there is a waitlist, it is our moral obligation to ensure we are promoting progress and increasing equitable access to lifesaving transplants," said Maureen McBride, UNOS' CEO.

Patient advocacy groups including the American Society of Nephrology, Global Liver Institute, National Kidney Foundation, and Renal Support Network support the bill. So does the American Hospital Association. In addition to allowing HRSA to conduct an open competition for OPTN operational contracts, the legislation would:

- Make technical changes to the National Organ Transplant Act of 1984;
- Broaden the eligibility for, and nature of, HRSA contract awards to ensure the OPTN doesn't have to be run by one entity;
- Give the Department of Health and Human Services more flexibility to manage OPTN contracts by removing a $7 million cap on direct HRSA funding of OPTN contractors; and
- Require a report by the Government Accountability Office to help Congress better understand how OPTN is financed.

Hospice Providers to Get $780 Million Pay Hike From Medicare

Hospice providers will see an additional $780 million in Medicare payments in fiscal year 2024 under a Biden administration rule released Friday.

The increase represents a 3.1% boost in the payment rate, according to the final rule (RIN 0938-AV10) from the Centers for Medicare & Medicaid Services.

Medicare's hospice benefit covers end-of-life care and services for beneficiaries who are terminally ill with a life expectancy of six months or less if the illness runs its normal course. Beneficiaries who enroll in the hospice benefit agree to forgo Medicare coverage for conventional treatment of their terminal illness.

In 2020, more than 1.7 million Medicare beneficiaries received hospice care and hospice providers earned $22.4 billion in Medicare payments, according to the Medicare Payment Advisory Commission.

Medicare Unveils Dementia Care Model for Patients, Caregivers

The Biden administration is launching a model that aims to improve the quality of life for people living with dementia and reduce strain on their caregivers, the Center for Medicare & Medicaid Services announced Monday.

The Guiding an Improved Dementia Experience Model seeks to help people remain in their homes and communities through a package of care coordination and management, caregiver education and support, and respite services, according to the CMS. "We've made tremendous progress in improving care for people

with dementia over the past decade," the CMS Administrator Chiquita Brooks-LaSure said at the National Alzheimer's Project Act Advisory Council meeting Monday.

"But people living with dementia and their caregivers too often struggle to manage their health care and connect with key supports that allow them to remain in their homes and communities," she said. The model provides a link between the clinical health care system and community-based providers to help people with dementia and their caregivers access education and support, such as training programs on best practices for caring for dementia patients.

The model will test an alternative payment for participants who deliver support service to people with dementia and will grant people with dementia and their caregivers access to a care navigator, according to the CMS. Helen Bundy Medsger, primary caregiver and health care advocate for two generations of her family who have suffered from Parkinson's disease with Lewy body dementia, said "this is a day that comes after many years of advocacy." "I have fought to see the day when health care and payer systems would more broadly recognize and address not only the physical, the cognitive and the psychiatric symptoms, but all aspects of care and support that affect our daily quality of life," Medsger said at the meeting. "Because we live with dementia every single day, we know the need is critical, and now our struggles are finally being acknowledged."

This new care model also supports the administration's goal of advancing health equity for underserved communities, the agency said in a statement. Hispanic, and Asian Americans, Native Hawaiian, and Pacific Islander populations have a higher prevalence of dementia, are less likely to receive a diagnosis, and have more unmet needs, the agency said. Applications for the eight-year model are expected to open in the fall, but letters of intent can be submitted to the CMS until Sept. 15.

The Alzheimer's advisory council meets quarterly to discuss the efficacy of government programs targeting the needs of individuals and caregivers who are coping with the consequences of Alzheimer's disease or dementia.

Long Covid Research, Practice Office Announced by HHS

The Department of Health and Human Services has announced the formation of the Office of Long Covid Research and Practice, according to HHS Monday.

The office will coordinate the government response to the longer-term effects of Covid-19, including Long Covid and associated conditions.

The National Institutes of Health has also announced the launch of the Long Covid clinical trials through the RECOVER Initiative, said the agency.

Medicare Prescription Drug Premiums Projected to Drop in 2024

Average monthly Medicare premiums for Part D prescription drug coverage are projected to drop to $55.50 in 2024, down 1.8% from $56.49 this year, the Biden administration announced Monday.

"Stable premiums for Medicare prescription drug coverage in 2024 are supported by improvements to the Part D program in the Inflation Reduction Act that allow people with Medicare to benefit from reduced costs," said a fact sheet from the Centers for Medicare & Medicaid Services.

In 2022, the CMS required Part D plans to apply "all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings at the pharmacy. This change is projected to decrease Part D beneficiary out-of-pocket costs by $2.62 billion in 2024," the fact sheet said.

The CMS announced the projected basic monthly premium—which is based on drug plan bids submitted to the agency—to help consumers understand cost trends before they select plan coverage for 2024 during Medicare open enrollment, which begins later this year.

The Medicare prescription drug benefit helps beneficiaries pay for brand-name and generic prescription drugs. More than 51 million Medicare beneficiaries are enrolled in the coverage.

The CMS also released the Part D national average monthly bid amount, which helps help Medicare prescription drug plans sponsors finalize their premiums in preparation for Medicare open enrollment for 2024 coverage.

This year's open enrollment period will run from Oct. 15 to Dec. 7, 2023. The CMS expects to release final 2024 premium and cost-sharing information for private Medicare Advantage and Part D plans this September.

LEGAL

Failure to Pursue Agency Remedy Dooms Provider's Billing Suit

A Texas-based cancer treatment center can't proceed with litigation involving a billing dispute with Medicare Advantage Organizations operated by UnitedHealthcare Inc., a federal court said.

Caris MPI Inc.'s failure to ask the US Department of Health and Human Services to resolve its claims against the insurer and its MAO subsidiaries before filing them in court doomed its lawsuit, the US District Court for the Northern District of Texas said Wednesday. The Medicare Act requires entities to exhaust claims at the administrative level before seeking judicial review, the court said.

The court also held that it had jurisdiction over the case under the federal officer removal statute. Caris provided cancer diagnostic testing to people insured by UnitedHealthcare even though it's not a member of the insurer's network. It used the same billing codes regardless of whether a patient was covered by a private health plan or a Medicare Advantage plan.

In 2020, UnitedHealthcare said that Caris used the wrong billing codes for Medicare Advantage patients, sought partial repayments, and tried recoup overpayments by offsetting them against current claims. Caris responded by suing UnitedHealthcare in Texas state court, and the insurer removed the case to federal court in 2021.

The federal officer removal statute broadly allows any entity "acting under" a federal officer or agency to litigate in federal court so long as it had a colorable federal defense and acted under a federal officer's directions with respect to conduct connected to or associated with those directions, the court said. UnitedHealthcare and its MAO subsidiaries were acting at the direction of the Centers for Medicare and Medicaid Services, with which they had contracted to help administer the Medicare program, the court said. The dispute over the billing codes was connected to or associated with those directions, because the government sets the reimbursement rates, it said.

There's a circuit split on whether MAOs can assert the federal officer removal statute, Judge Brantley Starr said. The US Court of Appeals for the Sixth Circuit has held that MAOs' ability to act independently and use health plan designs applied in the private insurance market meant that they weren't closely supervised or controlled by CMS, he said.

But the Texas-based district court is controlled by the US Court of Appeals for the Fifth Circuit, which has said that CMS closely supervises MAOs through its extensive regulations, monitoring, and supervision, Starr said. The judge was bound to follow that decision, he said.

The case is Caris MPI, Inc. v. UnitedHealthcare, Inc., N.D. Tex., No. 21-cv-3101, 7/26/23.

Provizor Loses Protest of Defense Agency's Physician Procurement

Provizor lost its challenge to the terms of the Defense Health Agency's $44 billion maximum value procurement seeking to award multiple contracts for dental, medical support, and physician services, the GAO said.

Provizor Federal Inc. failed to show that the procurement's self-scoring methodology for reviewing corporate experience is unduly restrictive of competition, the Government Accountability Office said.

According to Provizor, the procurement unreasonably allows only single award indefinite-delivery, indefinite-quantity contract holders to combine task orders. This allows them to increase the relevancy of prior experience, and therefore to increase their self-scores, by claiming a higher number of full-time equivalent workers. This puts offerors with multiple award contracts at a disadvantage, Provizor said.

But language in the agency's solictaition "does not create the potential scoring disparity Provizor alleges," the GAO said.

Proposal instructions in the solicitation clearly prohibit offerors from consolidating multiple task orders into a single row on a self-scoring worksheet to a achieve a higher score, the GAO said.

The agency seeks to award up to 5 contracts under the Medical Q-Coded Support and Services - Next Generation procurement, the GAO said.

The case is *Provizor Fed. Inc.*, GAO, B-421768, 7/26/23, decision released 7/28/23.

Settlement Reached in Termination Suit Backed by OSHA Mandate

A health-care worker reached a settlement in her wrongful termination lawsuit against an Illinois hospital that she alleged violated OSHA's general mandate for safe work environments by firing her for missing work due to Covid-19 symptoms.

Maria Cupi's filed her lawsuit against Carle BroMenn Medical Center in the U.S. District Court for the Central District of Illinois in October 2021.

- According to Cupi, she was directed to stay home by the hospital's Covid-19 hotline after she developed a fever.
- Per the hotline's recommendation, Cupi stayed home but was terminated upon returning to work, with her absence cited as a reason.

- Cupi alleged that Carle BroMenn violated the Occupational Safety and Health Act's general mandate requiring employers to provide employees with a work environment free from hazards that do or are likely to cause serious physical harm or death.

- The parties agreed to a settlement, according to a notice filed by Cupi.

Cupi's attorney couldn't immediately be reached for comment on the terms of the settlement. An attorney for Carle BroMenn declined to comment on the terms.

The case is Cupi v. Carle BroMenn Med. Ctr., C.D. Ill., No. 1:21-cv-01286, Filed 7/28/23.

Obamacare Fine Gives IRS Bankruptcy Priority, Sixth Circuit Says

The Affordable Care Act's penalty for individuals who don't have health insurance is a tax that the Internal Revenue Service can collect ahead of other creditors in a bankruptcy, the Sixth Circuit ruled.

The levy, known as the Shared Responsibility Payment, has "several tax-like qualities," the US Court of Appeals for the Sixth Circuit said in its Monday opinion. Additionally, the law that governed the individual mandate "keys a taxpayer's amount owed to household income," the court said. The court's ruling falls in line with decisions out of the Third and Fourth Circuits.

The finding is key for the IRS because US bankruptcy law offers priority to "unsecured claims of governmental units . . . [for] a tax on or measured by income," the court said.

From 2014 to 2018, the ACA mandated most Americans to purchase health insurance. If they failed to do so, they were required to pay a levy, known as the Shared Responsibility Payment. Though the penalty was abolished beginning in tax year 2019, it stirred up legal confusion over whether the payment was a penalty or tax under the law, which would determine whether the IRS would have priority in collecting the payment in a bankruptcy.

If the court decided the fine was a penalty, the IRS wouldn't be entitled to any payment priority in a bankruptcy.

This issue stems from the bankruptcy of appellant Howard D. Juntoff, who opted out of the health plan and didn't pay the penalty in 2018. After he declared bankruptcy, the IRS filed a proof of claim in bankruptcy court in an effort to collect the penalty.

The agency asked for priority above other creditors, arguing that claims from governmental units for taxes measured by income are entitled to priority, according to the filing. But the bankruptcy court denied the request, finding the penalty did not meet that standard.

Juntoff argued that the payment was not "measured by income" as "taxpayer liability turns on factors besides income, such as whether the taxpayer purchased health insurance," according to the filing. Lawyers for Juntoff didn't respond immediately to requests for comment.

This case is IRS v Howard Juntoff, 6th Cir. App., No. 22-3312, 7/31/23.

AROUND THE STATES

California

California Proposes $25 Million Threshold for Health M&A Deals

A California oversight agency proposed a $25 million annual revenue threshold for most health transactions that would trigger new notice requirements as a way to address rising medical costs.

The California Department of Health Care Access and Information released draft regulations Monday that lay out when a health-care company is engaged in a merger, acquisition, or other business deals that would trigger 90-day notification requirements be sent to a statewide board. The board would then have two months to decide whether it wants to conduct a formal cost-and-market analysis of the transaction to determine if the deal could have a negative impact on patient costs.

The draft regulations propose defining a transaction as "material" enough to warrant notification if the transaction is worth $25 million, or if a company expects its profits to increase by at least $10 million, or 20% because of the transaction.

In addition to the cost of the deal itself, the valuation of the companies also could lead to notification requirements. Businesses that make at least $25 million a year also would have to notify the Health Care Affordability Board. Any entity that makes at least $10 million a year and is working on a deal with a company worth at least $25 million also would have to report the transaction.

"So, if it's between $10 and $25 million annual revenue, and they're in a transaction with a $25 million annual revenue health-care entity, that's when the the materiality is met," Ashley Osak, an attorney in Polsinelli Law Firm's Los Angeles office.

The $25 million proposal in California lines up with similar thresholds set up in New York and Massachusetts. Massachusetts has a 60-day notification requirement for providers with more than $25 million in annual patient revenue. New York set a $25 million de minimus for a 30-day notice for health care transactions, under a law that's slated to take effect Tuesday.

However, the California agency wants the state's oversight to cover more transactions than New York's. The draft regulation released Monday includes insurers as well as pharmacy benefit managers, pharmacy middlemen that have come under fire from drugmakers and the Federal Trade Commission and are currently the target of a major reform effort in Congress. The New York law excluded both insurers and PBMs.

In general, the California draft rule exempts practices with 25 or fewer physicians, unless they're found to be charging a lot more compared to their counterparts for the same services.

The state office can't block any transactions, but it can forward its findings to the state attorney general's office.

The California office plans to hold a public meeting Aug. 15. The agency will receive comments through the end of August and plans to adopt the regulations before the end the year. It expects to begin receiving notices of material change transactions in January, for transactions that will be entered into as of April 1.

Patient's Father Can't Force Therapist to Turn Over Records

A California health-care provider can't be compelled to release a minor patient's medical records to her father absent proof that the provider acted in bad faith when she determined that the minor would be hurt by the records' release, a state appeals court said.

The father can't win a lawsuit alleging that his daughter's therapist violated a state law that entitled him to access the minor's medical records, because he didn't prove that the provider failed to determine if releasing the records would hurt the minor or that she acted in bad faith, the California Court of Appeal, First District, said.

The burden of proving that a provider made a "detriment determination" in bad faith is on the minor's personal representative, the court also said, deciding an issue of first impression.

Frank Vilches took his daughter—identified as Jane Doe—to licensed marriage and family therapist Michelle Leao for treatment. In 2018, he asked Leao to let him review Doe's medical records. Leao initially agreed, but later said that she'd determined that allowing Vilches to view the records would have a detrimental impact on her relationship with the patient, Doe's psychological well-being, and Doe's ability to trust in general, according to the court.

Vilches sued Leao for allegedly violating the state law regarding access to Doe's records. The trial court granted Leao summary judgment, saying her decision fell within the law's exceptions. The exceptions say that a provider's liability will attach only if their detriment decision is found to have been made in bad faith, it said.

The law unambiguously and broadly gave providers immunity from any liability, not just monetary damages, the appeals court said in affirming. Providers thus can't be compelled to disclose minor patients' records absent proof of ban faith, it said.

Nothing in the law suggests that a court must review the correctness of a provider's detriment determination, the court also said. This "makes logical sense" because untrained judges shouldn't be second-guessing providers' clinical judgment, it said.

Vilches never argued that Leao acted in bad faith, the court said. The only question was whether she made a detriment decision in the first place, and the answer to that question was clearly yes, it said.

Moreover, Leao clearly understood her obligations under the law, given that she referred to it and its exceptions when she told Vilches that she was denying his request, Justice Tracie L. Brown said in the July 28 opinion.

The case is Vilches v. Leao, 2023 BL 259828, Cal. Ct. App., 1st Dist., No. A163638, 7/28/23.