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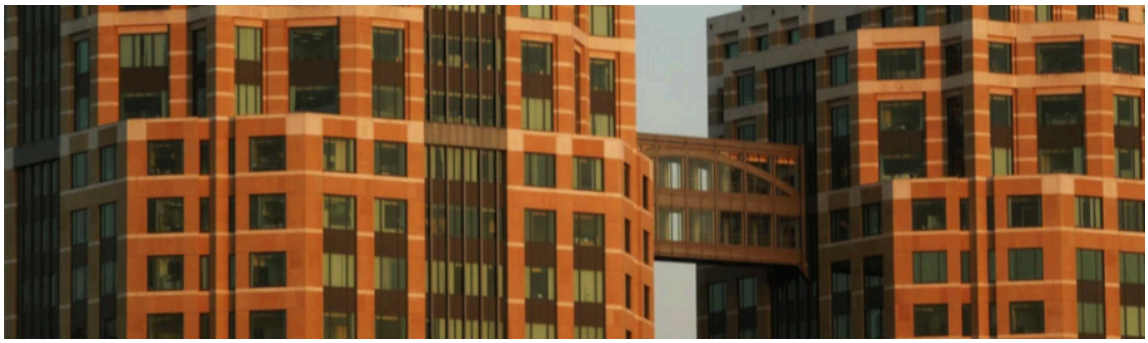
In Key Hearing, Federal Judge Expresses Doubt About Court's Ability To Take Action on Contract Pharmacy Matter

In **Federal, Judicial** February 11, 2021 **Tom Mirga**



A federal district judge in Oakland, Calif., on Tuesday expressed doubt that she had jurisdiction to require the U.S. Health and Human Services Department (HHS) to make drug manufacturers repay 340B hospitals for drug discounts that the companies have declined to provide on drugs dispensed by contract pharmacies.

According to an attorney who observed the Feb. 9 court proceedings online, U.S. District Judge Yvonne Gonzalez Rogers indicated that she did not think the court could order such repayments, given that the 340B statute called for the creation of a 340B program administrative dispute resolution (ADR) process to resolve 340B covered entities claims that they have been overcharged for drugs purchased under 340B.

Tuesday's late afternoon hearing, held remotely via videoconference, was on the federal government's motion to dismiss the lawsuit by five hospital associations, the association of hospital pharmacists, and three hospitals against HHS over the department's enforcement of its 340B contract pharmacy requirements for drug companies.

The hospital plaintiffs have asked the court to order HHS to require six drug companies—Eli Lilly, Sanofi, AstraZeneca, Novartis, United Therapeutics, and Novo Nordisk—to provide 340B discounts on drugs dispensed by contract pharmacies, to issue refunds to hospitals that were refused discounts, and to impose civil monetary penalties against the companies. HHS has asked Gonzales Rogers to dismiss the lawsuit, on the grounds that the new 340B ADR system should handle the matter, not the courts, as well as because there has not been a final HHS action for the court to review.

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A U.S. Health Resources and Services Administration (HRSA) final rule implementing the 340B ADR system took effect Jan. 12. The National Association of Community Health Centers (NACHC) and Ryan White Clinics for 340B Access (RWC-340B), both of which also are suing HHS over its response to the drug manufacturers' contract pharmacy actions, have both asked for their lawsuits to be stayed so that related petitions filed under the ADR system can be heard and decided.

Proceedings before the ADR panel were frozen on Jan. 21 when the new Biden administration withdrew former HHS Secretary Azar's Jan. 20 public notice of his appointment of six voting and two ex-officio non-voting members to the ADR board. Then, on Jan. 25, Pharmaceutical Research and Manufacturers of America (PhRMA) sued in federal district court in Maryland to strike down the federal final rule that established the ADR process.

During Tuesday's hearing in the hospitals' lawsuit, Gonzales Rogers asked their attorneys if the hospitals would withdraw their request for repayments for overcharges. She noted the availability of a remedy under the ADR system, and the stays in the health center and HIV/AIDS clinic lawsuits to allow ADR proceedings to go forward. William B. Schultz, counsel for the plaintiffs, said they would not withdraw their request for overcharge repayments because there is "no effective regulation yet." They also said the ADR process does not provide swift relief, and noted the withdrawn appointments to the ADR board and manufacturer lawsuits challenging the system's legality. Congress provided for swift relief in the form of HHS imposition of civil monetary penalties against the manufacturers, he said. Schultz served as General Counsel of HHS during the Obama Administration.

A significant portion of the hearing was devoted to debate over whether the court has jurisdiction to order HHS to impose civil monetary penalties; whether HHS has discretion to impose such penalties; and whether HHS abdicated its enforcement responsibilities. HHS attorney Kate Talmor said HHS has not abdicated its responsibility.

She said the government is (1) "investigating" the manufacturer actions, (2) determining what actions HHS should undertake, (3) HHS is working with providers to investigate and resolve the matter; (4) that the OGC issued the Advisory Opinion, (4) HHS is awaiting the appointment of a new Secretary under the new administration (as if HHS expects enforcement thereunder) and (5) that HHS has promptly promulgated ADR Regulations. The Judge took issue with HHS' use of the term "promptly" after years of delay and also questioned why, if the agency is not abdicating its duty, has it not issued CMPs in light of the Office of General Counsel's Advisory Opinion. Talmor said the court is not empowered to order specified enforcement actions, even when the agency declined to do so.

In response to a question from the judge regarding the status of the manufacturer pricing provisions in the Affordable Care Act, the HHS attorney conceded she did not know whether most of the actions were undertaken. For instance, she was not aware whether HRSA had moved forward with publishing ceiling pricing information on the Office of Pharmacy Affairs (OPA) web site. OPA unveiled the ceiling price database in 2019.

Judge Gonzalez Rogers told the attorneys that she hopes to make a ruling on the motion to dismiss very shortly. 340B Report will keep you updated on developments.

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House Set To Act on Bill that Could Result in Higher Medicaid Rebates and 340B Discounts

In **Federal, Legislative** February 11, 2021 **Tom Mirga**

The U.S. House Energy and Commerce Committee is scheduled to mark up COVID-19 relief legislation today with language that could cause pharmaceutical manufacturers to owe states Medicaid drug rebates worth more than a drug's average manufacturer price (AMP).

The language is in the Medicaid subtitle of the Democratic-controlled E&C committee's draft pandemic relief bill. Last week, House and Senate Democrats passed budget reconciliation bills, with the goal of tucking Democratic-approved COVID-19 relief in the final version and getting it passed by the Senate on a simple majority vote, rather than by filibuster-proof 60-vote supermajority. The E&C panel and other House committees are writing and voting on the parts of the relief bill under their jurisdictions. House Speaker Nancy Pelosi (D-Calif.) said last week she hoped to send the House bill to the Senate by the end of this month.

According to Michael McCaughan of drug manufacturer consulting firm Prevision Policy, the E&C committee's Medicaid rebate language "restores the Medicaid rebate formula for inflation" to as it was before the Affordable Care Act, "whereby manufacturers with sufficient histories of inflation can owe rebates over 100 percent" of AMP. "If this passes, some manufacturers will end up owing more in Medicaid rebates than the cost of the drug."

The formulas for calculating Medicaid rebates and 340B ceiling prices use the same drug price and rebate percentage variables. However, a 2017 340B program regulation stipulates that when 340B ceiling price formula would result in a ceiling price of zero, the manufacturer should charge $0.01.

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Both McCaughan and King & Spalding Partner John Shakow, who also represents drug manufacturers, said they assume the U.S. Health Resources and Services Administration (HRSA) under the Biden administration will leave the 340B "penny pricing" policy in place if the E&C committee's new Medicaid rebate language becomes law. It is very likely that 340B providers will push to have the provision apply to them.

Shakow said the committee's language "profoundly undermines" the compact between the federal government and drug manufacturers undergirding the Medicaid drug rebate program, now in its 30th year. If it becomes law, he predicted, "it certainly will lead manufacturers at the margins to leave" the program.

"If manufacturers leave the Medicaid program, however, they won't be obliged to offer discounts to 340B," Shakow continued. "So on net, I'd say this development has the potential to be harmful to 340B entities."

340B providers may not agree with that analysis. They are likely to argue that going back to the old formula makes sense and that drug companies should be penalized further if they significantly raise prices. They are also likely to make the case that drug manufacturers will still come out ahead since the commercial and Medicare markets are much bigger.

The three manufacturers of insulin sold in the U.S.—Eli Lilly, Sanofi, and Novo Nordisk—have "aggressively" raised the prices of their insulin products in recent years, the U.S. Senate Finance Committee concluded in a recent report. If the E&C drug rebate language becomes law, they might be among the first manufacturers to feel its sting.

On a separate front, the three insulin manufacturers are at the center of the battle over manufacturers' obligation to offer 340B pricing on drugs dispensed by contract pharmacies.

McCaughan said drug manufacturers likely will try to get the rebate language removed from the COVID-19 relief bill. If that's impossible, he said, they might try to replace it with language from the Senate Finance drug pricing bill from the last session of Congress. That language would have capped Medicaid rebates at 125 percent of AMP for products currently on the market, with no percentage limit for newly marketed drugs.

The current language reportedly has been "scored" as generating between $14 billion and $20 billion annually in savings to the federal government. The E&C committee reportedly will use those savings to pay for other Medicaid-related provisions in its pandemic relief bill.

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Hospital groups say 340B hospitals and the communities they serve will be devastated if the U.S. Supreme Court does not strike down a nearly 30 percent cut in the hospitals' Medicare drug reimbursement. | Shutterstock

Hospitals Ask U.S. Supreme Court to End "Crushing" Medicare Payments Cuts for 340B Drugs

In **Federal, Judicial** February 11, 2021 **Tom Mirga**

Three national hospital groups and three hospitals yesterday asked the U.S. Supreme Court to overturn a federal appeals court's 2-1 July 2020 decision that the nearly 30 percent cut since 2018 in 340B hospitals' drug reimbursement under the hospital outpatient prospective payment system (OPPS) "rests on a reasonable interpretation of the Medicare statute."

If the decision stands, the hospital plaintiffs said in their petition for review, the "rate cut will devastate 340B hospitals and the communities they serve."

The U.S. Health and Human Services Department (HHS) and the Center for Medicare & Medicaid Services' (CMS) reduced reimbursement rates "eviscerate the federal subsidy that has kept 340B Hospitals afloat for decades," the plaintiffs said. "Prescription-drug reimbursement rates to 340B hospitals are now nearly 30 percent lower, eliminating $1.6 billion annually to participating providers."

"Those cuts have inflicted a crushing blow on 340B hospitals, which are already eliminating essential services at a time when a deadly pandemic continues to ravage the nation," the plaintiffs continued. "Those cuts have likewise subverted the design of the 340B program, which Congress created for the purpose of subsidizing medical care to the poor through above-cost insurer reimbursements. Those damaging consequences underscore the pressing need for review by this court."

The hospital plaintiffs are seeking review on the narrow question of whether a Supreme Court precedent permits the U.S. Health and Human Services Department (HHS) and its Center for Medicare & Medicaid Services (CMS) "to set reimbursement rates based on acquisition cost and vary such rates by hospital group if it has not collected adequate hospital acquisition cost survey data."

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The Trump administration considered the drug reimbursement cuts for 340B hospitals one of its signature achievements to lower drug prices for patients. It partially justified the cuts on the grounds that it reduced some Medicare beneficiaries Part B prescription drug co-payments. Hospital groups have argued that it did not save patients a penny since the provision was budget neutral and therefore rates were raised on other Medicare services provided by hospitals.

The Trump administration in December published a final rule, effective Jan. 1, 2021, that continued the reduced average sales price (ASP) minus 22.5 percent reimbursement rate for hospitals' 340B-purchased drugs. The Biden administration has not said what its plans are for the cuts. Because the reimbursement reduction was already in effect before the new administration came into power, and because it is deeply woven into a CMS rule that sets payment rates for a multitude of other hospital outpatient matters, the new administration has virtually no leeway to reverse the cuts for 340B hospitals this year.

The Biden administration is perceived to be more receptive to hospitals' 340B program concerns than the last administration. Many provider stakeholders predict it will not continue the cuts in calendar year 2022.

In the meantime, there is a CMS drug reimbursement policy under challenge before the nation's highest court. And the Trump administration is no longer there to defend it.

The hospital plaintiffs—the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Northern Light Health of Maine, Henry Ford Health System of Michigan, and AdventHealth Hendersonville of North Carolina—focus their attack on CMS's decision in 2018 "for the first time [to] set a prescription-drug reimbursement rate for one hospital group different from the rate it set for all the others," namely, for 340B hospitals.

If CMS wished to do so, the hospital plaintiffs said, by law it needed to base the new reimbursement rate for 340B hospitals on "robust" acquisition cost survey data. Instead, the plaintiffs said, CMS relied on a Medicare Payment Advisory Commission report estimating the average minimum discount received by 340B hospitals. As a fallback if it lacked acquisition cost survey data, CMS instead had to calculate 340B hospitals' new reimbursement rate by reference to the drugs average sales price, the hospitals plaintiffs said. Instead, the plaintiffs said, quoting the federal district court that rules in their favor, CMS "sought to mimic the result" required by law "by setting rates designed to approximate acquisition costs."

The district judge ruled that effort was "a patent violation of agency authority," in a win for the plaintiffs. But last summer, a federal appeals court ruled that CMS had the authority to impose the nearly 30 percent cut, and interpreted that authority reasonably "so as to avoid reimbursing those hospitals at much higher levels than their actual costs to acquire the drugs."

The hospitals plaintiffs told the Supreme Court that the appeals court decision "raises an issue of exceptional importance that manifestly warrants this Court's review."

The plaintiffs said the appeals court "grievously erred in affirming HHS's misuse of its modest 'adjustment' authority" under the law "to make wholesale changes in the method for calculating reimbursement rates for 340B Hospitals—changes that flout the requirements Congress prescribed for setting such rates."

"And the policy the court upheld on the basis of this legal error affects billions of dollars in federal prescription-drug spending, and resulted in a $1.6 billion annual hit to 340B hospitals that depend on full Medicare reimbursements to subsidize essential healthcare services they provide to low-income communities," the plaintiffs said. "A legal error this serious upholding a federal agency action with consequences this grave is by itself a sufficient reason to grant review."

The Supreme Court rarely takes up a petition for review so the hospital effort is a long shot.

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The American Hospital Association says UnitedHealthcare's Specialty pharmacy coverage policies undermine the 340B program's intent. | Shutterstock

AHA Asks CMS to Rein In UHC's Specialty Pharmacy Policies

In **Federal, Judicial** February 11, 2021 **Tom Mirga**

The American Hospital Association (AHA) last week told the U.S. Centers for Medicare & Medicaid Services (CMS) that insurance company UnitedHealthcare's (UHC) specialty pharmacy coverage policies "undermine the intent of the 340B program" and should be disallowed.

In a Feb. 4 letter, AHA told CMS that UHC "is upending the traditional system" in which hospitals buy, store, and administer specialty drugs and then bill payers for the cost and administration of such drugs. It said UHC health plans "are no longer permitting many providers (under penalty of non-payment) to acquire and store a variety of drugs needed to treat their patients."

Instead, AHA continued, "the health plan demands that these providers accept drugs purchased and handled by the health plan, which in turn relies on" specialty pharmacies owned by or affiliated with OptumRx, UHC's pharmacy benefit management subsidiary.

Specialty drug "white bagging" and "brown bagging" under UHC's policies has implications not just for patient care, but also for hospitals' ability "to provide better access to care" through the 340B program, AHA said.

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"Contract or community pharmacy arrangements under the 340B program have allowed hospitals to improve access to prescription drugs for their communities," AHA said. "White or brown bagging drugs allows the insurer to control the distribution of the drug and would eliminate the role of 340B community pharmacy arrangements as well as undermine the intent of the 340B program to allow hospitals to use savings from discounted drugs to improve access to care for the vulnerable communities they serve."

AHA asked CMS to prohibit brown bagging—in which patients take possession of drugs and bring them to providers for administration—by UHC and all other health plans serving Medicare Advantage, Medicaid, Children's Health Insurance Program, and federally facilitated health insurance marketplaces. It also recommended stricter limits on white bagging—in which the plan's own or affiliated specialty pharmacy dispenses plan-purchased drugs to the provider for administration. "At no point should providers be required to accept these arrangements when they are unilaterally forced upon them by payers," AHA said. "Providers should be permitted to decline any such arrangements based on quality of care concerns."

Lastly, AHA said payers allowed to use white bagging "should be required to give sufficient and advance notice to providers."

"Oftentimes, providers learn about the payer implementation of these policies with little-to-no notice," AHA said.

340B Report reached out to UHC for its response to AHA's letter. The company told us:

"As of October 1, 2020, outpatient hospitals in UnitedHealthcare's commercial network are subject to an expanded requirement that requires additional specialty drugs to be sourced from indicated specialty pharmacies, unless otherwise authorized by UnitedHealthcare. Our data shows that, for some outpatient hospitals, the reimbursement rate on some specialty drugs may be over 400% of the reimbursement rate established by the Centers for Medicare & Medicaid Services (CMS) for the same drug. By requiring outpatient hospitals to source these drugs through an indicated specialty pharmacy, we are driving unnecessary costs out of the health care system to help make care more affordable. The specialty drug sourcing requirement only applies to outpatient hospitals in our commercial network.

UnitedHealthcare's contracted specialty pharmacies include major vendors like Accredo (owned by Cigna), CVS Specialty, Rx Alliance (owned by Walgreens), and others in addition to UnitedHealthcare's affiliated specialty pharmacy, Optum Specialty Pharmacy."

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If the U.S. Supreme Court were to decide that the entire ACA was unconstitutional, all of its 340B related provisions would be struck down.

Biden Administration Position in Supreme Court ACA Case Has 340B Implications

In **Federal, Judicial** February 11, 2021 **Tom Mirga**

The Biden administration late yesterday told the U.S. Supreme Court that, due to the change in the presidency, the federal government has changed its main position in the lawsuit over the Affordable Care Act's (ACA) constitutionality. The government now says the court should uphold the entire law.

If the Supreme Court were to decide that the entire ACA was unconstitutional, all of its 340B related provisions would be struck down. These include deeper 340B discounts (due to ACA's higher Medicaid drug rebate percentages), extension of 340B eligibility to rural and free-standing cancer hospitals, the fight over responsibility for preventing duplicate 340B discounts and Medicaid managed care rebates, the new 340B administrative dispute resolution process, and manufacturer civil monetary penalties for knowing and intentional overcharges.

The Trump administration argued in the case that ACA's individual insurance mandate is unconstitutional and, that as a result, the entire ACA is unconstitutional. In taking that stance, the Trump administration sided with the several red states that filed the lawsuit.

The Supreme Court heard arguments in the case in on Nov. 10. Although it could hand down its decision at any time, it habitually releases it biggest decisions toward the end its term, which should come in June or early July.

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Glaxo Smith Kline has notified 340B covered entities about the availability of refunds for overcharges early in 2019. | Shutterstock

Drug Manufacturers GSK and Esperion Offering Refunds for 340B Overcharges

In **Federal, Pharma Industry, Regulatory** February 11, 2021 **Tom Mirga**

Drug manufacturer Glaxo Smith Kline (GSK) yesterday notified 340B covered entities on the U.S. Health Resources and Services Administration (HRSA) website that it is offering refunds for overcharges on about two dozen NDCs during the first quarter of 2019.

In the notice, dated Feb. 1, GSK said it "intends to refund any amount equal to or in excess of $100 (aggregate for all applicable NDCs) for the periods listed directly to the 340B Covered Entity of record. Separate correspondence including a check and details of the payment will be sent to the 340B Covered Entity."

It added, "For 340B Covered Entities who may be owed less than $100 in aggregate or who have questions about the above-referenced recalculation for this period, GSK invites interested parties to contact it via email at GSK.340BRefunds@gsk.com, with a reference to the NDC and time period."

Drug manufacturer Esperion Therapeutics yesterday notified 340B covered entities on the HRSA website that it is offering credits for overcharges on its non-statin cholesterol-lowering drugs Nexletol and Nexlizet during the second and third quarters of 2020. Esperion said it is working with the 340B prime vendor, Apexus, to issue the refunds.

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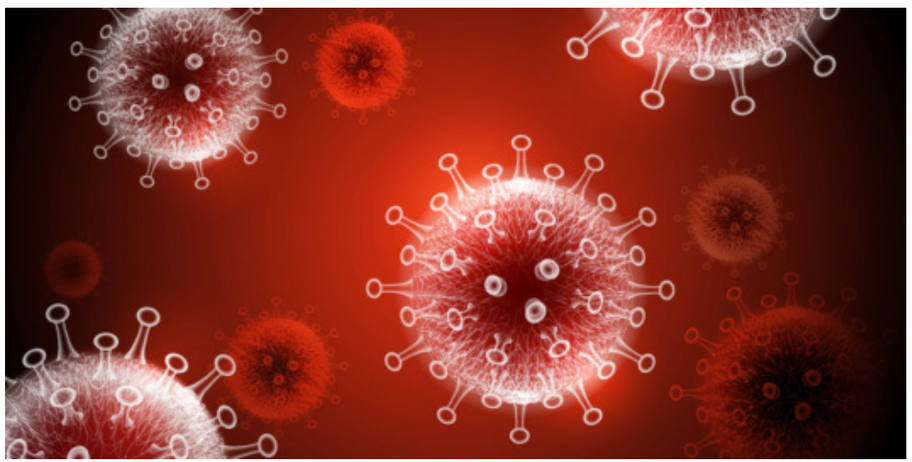

The National Association of Community Health Centers said its members have already begun vaccinating priority populations against the SARS-Cov-2 virus that causes COVID-19. | Shutterstock

Health Centers to Begin Receiving COVID-19 Vaccines Directly

In **Federal, Legislative, Regulatory** February 11, 2021 **Tom Mirga**

As soon as Monday, some federally qualified health centers (FQHCs) will be able to start ordering COVID-19 vaccines for administration to patients, under a "community health centers vaccination program" announced Tuesday by the Biden administration.

The administration said in a fact sheet that the health center program "is part of a broader effort to ensure all communities are being reached in the national push to get people vaccinated." It said, "The program will be phased in, with the first centers able to start ordering vaccines as early as the week of February 15. The initial phase will include at least one Community Health Center in each state, expanding to 250 centers in the coming weeks."

The National Association of Community Health Centers (NACHC) said that, once currently limited supplies of COVID-19 vaccine begin to increase, the U.S. Health Resources and Services Administration and the U.S. Centers for Disease Control and Prevention "will support vaccination in additional targeted health centers."

NACHC said its members "have already started vaccinating priority populations in many states. Getting direct allocations of the vaccines will help ramp up efforts already underway on the ground to ensure minorities and special populations are protected."

The COVID-19 relief legislation that the U.S. House Energy and Commerce Committee is marking up today "invests $7.6 billion in Community Health Centers" during the current fiscal year, which is almost half over, according to a committee memo. The money is to be used for COVID-19 vaccine-related activities, COVID-19 tracking and tracing, equipment and staffing, community outreach, and "to modify, enhance, and expand health care services and infrastructure."

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U.S. Sen. Richard Burr (R-N.C.) succeeds retired senator Lamar Alexander as the highest-ranking Republican on the Senate HELP Committee.

Burr Named Ranking Republican On Committee with 340B Oversight

In **Federal, Legislative** February 11, 2021 **Tom Mirga**

As expected, U.S. Sen. Richard Burr (R-N.C.) on Tuesday was formally named the highest-ranking Republican member of the Senate Health, Education, Labor, and Pensions (HELP) committee, the Senate committee with jurisdiction over the 340B program.

"As Ranking Member of the HELP Committee, I intend to conduct vigorous and appropriate oversight of the federal government and relevant agencies, many of which need significant reforms to better meet their public health mission," Burr said in a statement. "I intend to ask tough questions and to get real answers. I look forward to working with my colleagues—on both sides of the aisle—as we tackle the most pressing issues confronting our nation."

Also on Tuesday, U.S. Sen Mike Crapo (R-Idaho) was formally announced as the highest-ranking Republican on the Senate Finance Committee, which has jurisdiction over Medicare and Medicaid.

In a news release, Crapo said his priorities for health care include ensuring access, making care more affordable, ensuring a variety of coverage options, and strengthening the safety net. He also listed the COVID-19 pandemic and ensuring Medicare's long-term solvency.

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Neither the HELP nor the Finance Committee has scheduled hearings yet on President Biden's nomination of California Attorney General Xavier Becerra to be U.S. Secretary of Health and Human Services (HHS). The Los Angeles Times reported yesterday that "the GOP is fixated on rejecting" Becerra due to "perceived political and policy sins."

"GOP operatives are portraying Becerra at once as a leftist radical who will impose socialized medicine and a healthcare dilettante who will be manipulated by big insurance companies," the newspaper said.

"My main beef is this needs to be someone with deep experience willing to take on the healthcare industry," U.S. Sen. Mike Braun (R-Ind.) was quoted as saying.

"There really is a consensus that Becerra is the worst of the nominees," a GOP official close to U.S. Sen. Tom Cotton (R-Ark.), who is leading the nominee vetting process, told the newspaper. "Our most moderate members and our most conservative members feel it will be hard to stop any of these nominees, but if there is one, Becerra ought to be the one who goes down."

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