Consolidated Appropriations Act: Implications for Healthcare and Life Sciences Companies

December 30, 2020

On December 27, 2020, President Trump signed into law the Consolidated Appropriations Act (the "Act"), a massive coronavirus relief and spending bill. At over 5,000 pages, the Act provides funding for economic relief and public health measures to address the pandemic, and also includes regulatory provisions with significant implications for healthcare and life sciences companies. The Act includes provisions aimed at ending so-called "surprise billing" (enacted as the "No Surprises Act"); extending the priority review voucher program for rare pediatric diseases; modernizing generic drug labeling; increasing the transparency of licensure, patent, and exclusivity information for biological products; funding vaccines, therapeutics, testing, and medical supplies to combat the COVID-19 pandemic; and providing the Federal Trade Commission ("FTC") with the ability to seek civil penalties for deceptive claims related to COVID-19. We address these key developments below.

The No Surprises Act

The No Surprises Act, the core terms of which go into effect on January 1, 2022, contains a detailed set of provisions aimed at ending so-called "surprise billing." Surprise billing occurs when a patient is subject to treatment under circumstances where there is little or no control over the choice of provider, including treatment: (i) at an out-of-network emergency department; (ii) at an in-network hospital where the provider is out of network; or (iii) in connection with the use of an air ambulance where the provider is out of network. The No Surprises Act provides that patients in these circumstances will be required to make only cost-sharing payments consistent with what they would have paid had they been in network (with certain exceptions). It is important to note that the No Surprises Act instructs the Department of Health and Human Services to engage in rulemaking with respect to certain provisions; this rulemaking will likely play a meaningful role in shaping how the No Surprises Act is implemented.

Below is an overview of the new statutory treatment for each of these service categories:

- *Emergency services*. If a health insurer provides coverage for emergency services, the insurer generally must provide coverage for a beneficiary treated in an out-of-network emergency department and the insurer cannot require the beneficiary to pay more than the patient's in-network cost-sharing amount (*e.g.*, a standard co-pay). The insurer must pay the provider an amount that is either specified by state law (as may be the case in states with "surprise billing" statutes), negotiated between the parties, or determined by the Independent Dispute Resolution ("IDR") process described below.

- *Non-emergency hospital services*. If a patient is treated at an in-network facility (including hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgery centers) by an out-of-network provider, the payor cannot require the beneficiary to pay more than the patient's in-network cost-sharing amount. The insurer must pay the provider an amount that is specified by state law, negotiated between the parties, or determined through the IDR process.

- *Air ambulances*. A payor that covers air ambulance services must cover out-of-network air ambulance services and cannot require the beneficiary to pay more than the in-network cost sharing amount. The IDR process will apply if the payor and air ambulance provider cannot agree on reimbursement rates.

- *IDR process*. If a provider and payor cannot agree on a reimbursement amount, either party may initiate the IDR process, with matters resolved by arbitrators certified by the federal government.[1] For efficiency, certain types of claims can be batched together and resolved at once. The arbitrator is obligated to select one of the proposals made by the parties (as in Major League Baseball arbitration), and the losing party is required to pay arbitration fees.

  In deciding which proposal to select, the arbitrator should consider the "qualifying payment amount," which in 2022 will be the 2019 median in-network reimbursement amount for the same service in the same geographic market (with adjustments in subsequent years). The arbitrator may also consider factors including: (i) the level of training, experience and quality outcomes by the facility or provider; (ii) the market share held by facility or provider or the market share of the payor in the geographic region in which the service was provided; (iii) the complexity of the service furnished; (iv) the teaching status, case mix, and scope of services provided by the out-of-network facility; and (v) demonstration of good-faith efforts (or lack thereof) by the parties to enter into network agreements and, where applicable, contracted rates between the provider/facility and payor during the prior four plan years. Notably, however, the arbitrator cannot consider a provider's "usual and

[1] The description that follows is for the IDR process to resolve disputes between providers/facilities and payors.

customary charges" or reimbursement rates provided by government payors such as Medicare and Medicaid (which are typically substantially lower than rates paid by commercial insurers).

- *Balance billing*. With respect to the emergency and non-emergency services described above, a provider is generally not permitted to "balance bill" the beneficiary for the difference between the amount charged by the provider and the payor's allowed amount. The No Surprises Act, however, allows an exception to the bar on balance billing for non-emergency care provided by certain types of out-of-network providers if specific patient notice and consent requirements are satisfied. The patient must, among other things, be informed that the provider or facility is out of network and must also be provided: (i) a good-faith estimate of the applicable charges; (ii) in the case of an in-network facility and out-of-network provider, a list of in-network providers who are able to provide the same services and a notification that the beneficiary may choose such a provider; and (iii) information about whether prior authorization or other limitations may be required in advance of receiving care. Consent waivers cannot be requested by providers of emergency medicine services or certain specified "ancillary" non-emergency services offered at an in-network facility.[2]

It remains to be seen how relationships between payors and providers will be impacted by the statute. The statute gives providers the opportunity to commence arbitration proceedings if they believe payors are offering insufficient reimbursement. The IDR process appears to be designed to incentivize the parties to act with prudence. For instance, the "baseball-style" arbitration rules discourage parties from making overly aggressive demands (as the arbitrator is required to award an amount proposed by a party) and the requirement that the losing party pay the arbitrator's fees may discourage parties from bringing questionable cases. That said, the IDR process may ultimately favor larger provider groups that have the resources and sophistication to bring IDR proceedings; smaller provider groups may be inclined to reach network agreements with payors or consolidate with larger provider groups.

Additional Provider Funding

Congress appropriated an additional $3 billion for the "Provider Relief Fund," originally established in the Coronavirus Aid, Relief, and Economic Security Act, which provides

[2] The notice and consent provisions do not apply to "ancillary services" provided at an in-network facility, including emergency medicine, anesthesiology, pathology, radiology and neonatology; certain diagnostic services; items/services provided by specialty practitioners identified by the federal government through rulemaking; and services provided by an out-of-network provider if there is no in-network provider at the facility.

funding to providers who treat actual or possible COVID-19 patients.[3] Further, Congress specified that not less than 85% of "unobligated" balances of previously allocated funds should be made available to qualifying healthcare providers who submit applications seeking reimbursement for eligible COVID-19-related expenses or losses occurring in the third or fourth quarter of calendar year 2020 or the first quarter of 2021. As we have discussed previously, providers who receive this funding should ensure that they are compliant with applicable terms and conditions—and be prepared to document compliance—because under certain circumstances noncompliance could create liability under the False Claims Act.

Rare Pediatric Disease Priority Review Voucher Program

This program was created in 2012 and is intended to encourage development of therapies for rare pediatric diseases. Companies that obtain Food and Drug Administration ("FDA") approval for such therapies receive vouchers from the FDA that allow the companies to obtain a priority review for a subsequent drug application. These priority review vouchers, like those received through other programs, can be sold to third parties and thus are valuable assets in their own right. The program was set to expire this year, but the Act extends the program and allows FDA to continue awarding priority review vouchers for drugs that are designated as eligible no later than September 30, 2024, and approved no later than September 30, 2026.

Generic Drug Labeling Changes

The Act includes the Making Objective Drug Evidence Revisions for New Labeling Act (the "MODERN Act"), granting FDA the authority to address the outdated labeling of certain generic drugs. In general, manufacturers of generic drugs may only change the drugs' labeling after the labeling for the reference listed drug (the "RLD") is changed. This presents a problem, for example, when approval for the RLD has been withdrawn and there is no labeling to update; manufacturers of generics are left without the ability to update labeling to respond to new safety information. The new provisions allow for FDA to identify and select certain generic drugs for which: (i) the RLD approval has been withdrawn for reasons other than safety or effectiveness, and (ii) updated labeling with new scientific evidence or other information would benefit public health. The MODERN Act provides the process for updating generic labeling, which includes notice from FDA to generic drug manufacturers and the ability for those manufacturers to discuss and negotiate the proposed changes with FDA. The MODERN Act also provides FDA with the authority to order labeling changes. It is important to note that, from a product liability perspective, the MODERN Act requires FDA to initiate labeling updates and places no obligation on generic manufacturers to proactively update their own labels.

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[3] We have previously discussed this fund here, here, here, and here.

Patent and Exclusivity Information for Biological Products

The Act aims to increase the transparency of licensure, patent, and exclusivity information for biological products by requiring the information to be publicly available and updated every 30 days. For example, new biologics may receive 12 years of market exclusivity before biosimilar applications may be approved; however, it is often challenging for companies developing biosimilars to find up-to-date information on exclusivity periods for currently marketed biological products. These provisions essentially codify and set requirements for FDA's "Purple Book," an online database that contains information applicable to biological products (analogous to FDA's long-standing "Orange Book," which applies to non-biologics).

Funding for Vaccines, Therapeutics, Testing, and Medical Supplies

The Act allocates $23 billion to the Public Health and Social Services Emergency Fund with the overarching goal of developing countermeasures and vaccines, prioritizing U.S.-based manufacturing capabilities, and purchasing vaccines, therapeutics, diagnostics, medical supplies and medical surge capacity. Congress also allocated an additional $22 billion to facilitate testing, contact tracing, and surveillance. The Centers for Disease Control and Prevention will receive additional funds to plan, prepare for, promote, distribute, administer, monitor, and track coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage.

FDA Appropriations

The Act allocates $55 million for FDA to respond to the COVID-19 pandemic by supporting the development of necessary medical countermeasures and vaccines, monitoring medical product supply chains, facilitating new and emerging approaches for manufacturing medical products, and investing in public health research and response.

COVID-19 Consumer Protection Act

The COVID-19 Consumer Protection Act (another set of provisions included in the Act) provides that, for the duration of the COVID-19 public health emergency, deceptive claims that a product or service can treat, cure, prevent, mitigate, or diagnose COVID-19 will be treated as a violation of an FTC trade regulation rule defining an unfair or deceptive act or practice. Anyone who violates such a rule "with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule" may be liable for civil penalties for each violation. Although it is currently unlawful to make deceptive claims outside the public health emergency, the new provisions increase legal exposure by authorizing the FTC to obtain civil penalties (in addition to existing remedies).

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