

February 4, 2021

Elizabeth Richter
Acting Administrator
Center for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: UnitedHealthcare Coverage Policies

Dear Ms. Richter:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to express deep concerns regarding a series of UnitedHealthcare health plan coverage policies. These new restrictions will create significant barriers to access to necessary diagnostic and specialty pharmacy services for tens of millions of health plan enrollees.

As health care premiums continue to grow, the health insurance industry has launched a multipronged strategy to drive more consumer dollars to their bottom lines despite federal and state laws that attempt to limit how much profit health insurers can make at the expense of their subscribers. UnitedHealthcare has been particularly aggressive in developing and employing these tactics. UnitedHealth Group, UnitedHealthcare's parent organization, is the seventh largest company in America with more than \$250 billion in annual revenue. While it dominates in many health care coverage markets (and, indeed, is the largest commercial health insurer in the country), its fastest growing lines of business fall under the "Optum" portfolio of companies, which offer a diverse group of services from direct patient care through its network of 50,000+ employed or affiliated physicians and other owned/managed providers, essential services such as health care analytics, the management of pharmacy services, and the direct provision of specialty therapeutics.

Two of UnitedHealthcare's recent policy restrictions raise significant concerns about the impact on its enrollees and the stewardship of scarce health care resources, including taxpayer dollars. Much of the company's overall revenue is from government payers,

both due to enrollment in its UnitedHealthcare Medicare and Medicaid health plans and the increasing amount Medicare and Medicaid providers spend on administrative services that UnitedHealth Group has acquired.

In the following attachments, we identify two policy restrictions that warrant immediate attention by the Centers for Medicare & Medicaid Services (CMS) in its oversight of health plans serving enrollees in Medicare Advantage, Medicaid managed care, Children's Health Insurance Program and Health Insurance Marketplace health plans:

1. UnitedHealthcare's **Designated Diagnostic Provider program**, which could eliminate coverage for diagnostic tests at most freestanding and hospital labs while continuing to portray these providers as "in-network" to health plan enrollees. This policy would result in substantial confusion among patients about which providers are covered by their health plan, and, as a result, also likely increase the incidence of surprise medical bills that will not be prevented by recent changes in federal law.
2. UnitedHealthcare's **specialty pharmacy coverage policies** that disrupt care for patients with highly complex medical conditions and decrease providers' ability to control the quality of care for patients.

We urge you to use your oversight authority to protect UnitedHealthcare's enrollees by preventing it from implementing the diagnostic and specialty pharmacy coverage restrictions for health care coverage products regulated by the agency. These restrictions are described in depth in the attachments to this letter. We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Terrence Cunningham, director of policy, at tcunningham@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations & Public Policy

Attachment 1: Laboratory and Diagnostic Services
Attachment 2: Specialty Pharmacy Policies

Attachment 1: Laboratory and Diagnostic Services

Starting July 1, 2021, UnitedHealthcare's Designated Diagnostic Provider (DDP) program proposes to eliminate coverage for diagnostic tests at all freestanding and hospital labs, including those in its network, unless the facilities are an established DDP. The health plan has indicated that it anticipates expanding this policy to other types of diagnostic services in the future. In order to become a DDP, freestanding and network labs must complete a programmatic registration process by February 28 and meet a UnitedHealthcare-determined threshold for quality and efficiency. If a patient obtains care at a non-designated laboratory – even those supposedly “in-network” – coverage for their services will be denied, and the patient will be responsible for payment in full. In short, the DDP program is attempting to redefine the concept of an “in-network” provider and limit patient access to a much smaller pool of laboratory service providers. Because the enrollees' plan materials still will identify these non-designated labs as “in-network” providers, this policy will create significant confusion for those seeking care and could result cost-sharing obligations beyond the limits established under federal law.

- **Network Adequacy Implications.** Health insurance plans sold on the Health Insurance Marketplaces must have adequate provider networks under federal law. This is a core consumer protection and is linked to other consumer protections, including limits on how much a patient may be charged in cost-sharing during a given year.

Beneficiaries are most likely to seek care from in-network providers given their understanding that care from such providers will be covered by their plan. Indeed, many (if not most) consumers evaluate their plan options based on the provider network that would be available to them. In fact, UnitedHealthcare encourages patients to select their health plan by considering the network status of providers in their area to ensure that it meets their needs.¹

Under UnitedHealthcare's DPP program, a lab may be listed as being in-network but, in reality, the plan will not cover services provided by the lab. This undermines the patient's understanding of their network and likely the contractual agreement they have signed with the insurer. It also could mislead state and federal regulators about the sufficiency of the health plan's network.

The DPP program will not only create confusion among enrollees, but also ordering clinicians seeking laboratory services for their patients also are likely to be confused. These clinicians often rely on a health plan's provider directory to identify an appropriate site of care when referring patients. Because

¹ <https://www.uhc.com/understanding-health-insurance/types-of-health-insurance/understanding-hmo-ppo-epo-pos>

UnitedHealthcare's proposal does not change a non-DPP laboratory's network status, there is a very high risk that a clinician will inadvertently direct a patient to seek care from a non-designated laboratory provider with the financial consequences falling to the patient.

- **Out-of-Pocket Cost Implications.** Under federal law, most health plans, including those sold through the Health Insurance Marketplaces, must ensure that patient cost sharing does not exceed a maximum threshold. These rules apply primarily to in-network, covered services (although some out-of-network costs accrue as well, such as those for emergency services). UnitedHealthcare's DPP policy evades these rules by claiming unilaterally and after the enrollee has agreed to the terms of the contract that the services, while "in-network," are not covered at this particular site of care. As previously mentioned, there is a very high likelihood that patients could inadvertently seek covered services from these supposedly "in-network" providers only to face much higher cost sharing that presumably will not count toward their maximum out-of-pocket costs as the health plan has determined that they are not covered services at that site of care. In short, it appears UnitedHealthcare is deliberately manipulating the out-of-pocket maximum statutory requirements by exploiting the terms "covered" and "in-network."

This is particularly egregious, as health care stakeholders have worked with Congress for the past two years to protect patients from surprise medical bills. UnitedHealthcare's new policy undermines the No Surprises Act. Because UnitedHealthcare is deeming these services "in-network," patients who are surprised by medical bills resulting from this policy will not be afforded the new protections under the law.

Recommendation:

We urge CMS to disallow the implementation of the DPP policy in products that it oversees. This program will mislead enrollees with inaccurate portrayals of their access to care and put them at risk of additional health care costs when they are unable to keep up with UnitedHealthcare's attempts to manipulate familiar insurance terms like "in-network" and "covered."

Attachment 2: Specialty Pharmacy Policies

UnitedHealth Group is driving a significant change in the drug supply chain through its OptumRx subsidiary. Under new specialty pharmacy coverage policies, UnitedHealthcare 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, the health plan demands that these providers accept drugs purchased and handled by the health plan, which in turn relies on the OptumRx chain of owned and affiliated specialty pharmacies. These actions pose significant risks to quality of care as providers have inadequate control in ensuring patient access to high quality drugs as well as the appropriate storage and handling of those drugs.

Traditionally, the acquisition of and payment for drugs administered in a hospital setting was managed using the “buy and bill” model, which requires a provider to purchase, store and administer drugs, after which payers reimburse providers for both the cost of the drug and the administration of the drug. UnitedHealth Group is upending the traditional system, potentially sacrificing patient safety and quality care to benefit its profit margins. Specifically, the company increasingly is implementing policies known as “white bagging” and “brown bagging” in its health plan products:

- **White bagging:** The practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. Instead, a third party specialty pharmacy dispenses the drug and sends it to a hospital or physician office on a one-off basis.
- **Brown bagging:** Similar to white bagging, the provider is not permitted to procure and manage the handling of the drug used in patient care. However, in this instance, the third party specialty pharmacy dispenses the drug directly to a patient who then brings the drug to the hospital or a physician’s office for administration.

White and brown bagging policies present a number of challenges for patients and providers that warrant closer scrutiny by regulators:

- **Patient Care.** White bagging has implications for the safe care of patients requiring certain drug therapy treatments. The difficulties that white bagging policies place on cancer patients are a prime example of the potential harm. Specifically, many cancer patients are seen the same day as their scheduled infusion. Depending on a patient’s lab results and clinical presentation, initial treatment plans may be amended or cancelled altogether. Similarly, when oncologists use CT scans, infusion regimens may need same-day adjustments

depending on the progression of the disease shown in the CT scan results. When either of these situations occur, not having the new infusion regimen immediately available at the hospital can cause delays in treatment, ultimately increasing risk for the patient and potentially adversely impacting cancer patients' recovery.

- **Patient Access to Medication.** White and brown bagging policies have the potential to directly delay or disrupt the administration of a particular drug to a patient. For example, as the purchasers of pharmaceutical products under these policies, payers, not providers, are responsible for ensuring delivery of the product. However, this practice, especially in brown bagging situations, places significant reliance on the on-time delivery of product. Since these products are ordered on a patient-by-patient basis, as opposed to in bulk by hospitals, the potential for delay in care due to late or mistaken delivery of a product is a realistic outcome. In addition, brown bagging situations, in particular, could result in drug diversion.

Moreover, changing the distribution of outpatient drugs has implications for the 340B Drug Pricing Program. This program allows providers that care for a large number of low-income and uninsured patients to stretch their scarce federal resources to provide better access to care, including, but not limited to, improved access to outpatient prescribed pharmaceuticals. Contract or community pharmacy arrangements under the 340B program have allowed hospitals to improve access to prescription drugs for their communities. 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.

- **Planning and Preparedness.** To ensure the highest quality of care and patient safety, providers must have a clear line of sight into the acquisition, storage and administration of medications. White bagging and brown bagging remove providers from this process, creating significant, avoidable challenges that directly impact patient safety protections. For example, under the “buy and bill” model, hospitals are the purchasers and owners of medications necessary for patient care. This purchaser/ownership role allows providers to manage inventory; monitor dispensing, compounding, and dosing; and ensure proper preparation and storage of drugs from purchase through administration. White and brown bagging policies interrupt that process and require hospitals to receive and store product that is not their own with little-to-no notice. As a result, these

policies have the potential to overwhelm hospital storage capacity or surprise hospital supply chain and pharmacy personnel as product is delivered, which has the potential to violate individual hospital supply acquisition guidelines. Further, because these drugs are ordered for specific patients, tracking and keeping record of each patient-specific product presents an unreasonable and resource-intensive challenge.

- **Quality of Handling.** More complex medications require increased care and attention to ensure product quality control. When hospitals control and own medications, they can guarantee the point of origin of the drug and are responsible for and can demonstrate a clear chain of custody to ensure the highest quality product. White bagging and brown bagging, however, interrupt that process, disrupting a hospital's ability to guarantee the safety of such drugs firsthand. For example, when a payer implements a white bagging policy for a specific drug, the hospital is unable to dictate where the product is manufactured or if it met storage requirements, like refrigeration, prior to delivery to the facility. In addition, certain drugs have very limited windows for use once mixed or compounded, further complicating matters and adding to concerns around excessive product waste.
- **Information on Drug Shortages.** Prior to the utilization of white and brown bagging policies, hospitals were armed with more information to manage, address, and navigate drug shortages because they had clear line of sight into the medications their patients required. With the implementation of these new policies, hospitals are no longer responsible for the purchasing of pharmaceutical products, but still are left with the real consequences that drug shortages present, like alternative medication options and potential delay of receiving a specific drug. Further, removing hospitals from this juncture in the acquisition process limits provider access to critical data and information necessary to adapt to unanticipated challenges that may arise.
- **Inappropriate Shift in Liability.** Providers have primary responsibility for the safety of their patients. As white and brown bagging policies continue to expand, the primary onus for patient safety remains with providers despite health plans stripping those providers of their control over the quality and handling of drug therapies. This shift represents an inappropriate distribution of responsibility to be shouldered by providers, who no longer own or manage the acquisition of certain pharmaceutical products. For example, as drug therapies become more complex, they require significant resources and focus when it comes to storage, dispensing, compounding and administration. Given the significant liability attached to any error in preparation or administration, and without appropriate

provider opportunity to oversee the acquisition process due to white and brown bagging, hospitals are more likely to feel compelled to refuse to administer products under these conditions because they cannot guarantee their safety or efficacy.

Recommendations:

We urge CMS to take action to ensure access to quality care and drug therapies is not compromised through white or brown bagging policies. **Specifically, CMS should require health plans serving the Medicare Advantage, Medicaid, Children's Health Insurance Program, and Federally-facilitated Health Insurance Marketplace Health, including those offered by UnitedHealthcare, to comply with the following policies:**

- **No Brown Bagging.** Brown bagging should be prohibited. Shipping pharmaceutical products that require provider administration directly to patients presents significant and serious patient safety issues. Specifically, there is no method to guarantee proper storage of these drugs and the risk of drug diversion increases.
- **Prohibitions on Certain White Bagging.** There are some situations where white bagging poses significant risks to patient care. For example, drug doses for certain patients are dependent upon the results of lab tests and, therefore, dosing levels could change over the course of a treatment based on those test results. White bagging policies severely hinder a provider's ability to adapt and change dosing as necessary, at best, delaying needed patient care. In order to eliminate this potential harm, policies should be implemented that prohibit white bagging when the dosage or compounding of a pharmaceutical product is dependent upon the results of a patient's lab tests.
- **Safety Criteria for When White Bagging Can Apply.** In instances where white bagging is not prohibited, it should be restricted, allowing the practice only when certain criteria are met. Specifically, the practice should be restricted to the following situations. First, the practice only should be permissible in instances where the provider and health plan agree through their standard negotiations that such arrangements are in the clinical best interests of the patient. For example, certain providers, such as smaller or more rural facilities, may prefer to partner on some pharmacy operations in which case white bagging may present a reasonable solution. However, providers must be a joint partner in setting the terms of the agreement, including the quality and safety criteria, and have shared oversight of the specialty pharmacy arrangement. Second, there may be instances where white bagging policies are necessary to ensure patient access

to a medication. In those cases, specific safety criteria should be satisfied before any white bagging policy is permissible. Finally, at no point should providers be required to accept these arrangements when they are unilaterally forced upon them by payers. Providers should be permitted to decline any such arrangements based on quality of care concerns.

- **Provider Notice.** Oftentimes, providers learn about the payer implementation of these policies with little-to-no notice. When permitted to utilize white bagging, payers should be required to give sufficient and advance notice to providers to mitigate any gaps in critical information and secure the type of agreement referenced above.