November 9, 2020

Via Electronic Communication

Lewis G. Sandy, MD, FACP
Executive Vice President, Clinical Advancement
UnitedHealth Group
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Re: UnitedHealthcare's Accumulator Adjustment Medical Benefit Program Provider Protocol

Dear Dr. Sandy:

The undersigned patient advocacy organizations and professional associations are writing about the recent decision by UnitedHealthcare (UHC) to implement an accumulator adjustment program (AAP) for its medical benefit program. We are concerned that such program will negatively impact patients' ability to access and afford their medications and providers' financial stability, especially amidst the COVID-19 pandemic and the resulting economic recession. This also creates an undue burden on providers who are already stressed due to complicated prior authorization processes and claims denials. We are also concerned that this change could violate certain state laws. As such, we encourage UHC not to implement the AAP.

A. UHC's Accumulator Adjustment Medical Benefit Program

Recently, UHC sent a letter to health care providers detailing the provider protocol for UHC's "Accumulator Adjustment Medical Benefit Program." The letter notes that, effective January 1, 2021, the protocol requires network providers to submit payment information received from the drug manufacturer copay coupon programs, which will then be applied to the member's cost sharing responsibilities when billing for specialty medications as medical benefit drug claims. While not explicitly stated, it is assumed that any value that the member derives from the copay assistance will not be counted toward the member's deductible or maximum out-of-pocket limit given that the protocol says that its purpose is to "align employer costs for specialty medications with actual member out of pocket and deductibles."

B. Impact of UHC's AAP on Patients

Historically, privately insured individuals who cannot afford their copayments or coinsurance have been able to obtain aid from copayment assistance programs and the value of the assistance has contributed toward the patient's deductible and maximum out-of-pocket limit. These programs have been especially helpful for individuals enrolled in high deductible health plans in which the patient is required to pay significantly high out-of-pocket costs until the deductible is reached. However, under UHC's AAP, once copayment assistance runs out, the plan enrollee is again faced with an inability to afford his or her medication. In most instances, there are no generic alternatives, and patients may be forced to ration their medications or abandon treatment altogether.[1] For example, a recent study of patients with autoimmune conditions showed that four times as many patients discontinued taking their medication in plans that had implemented a copay

[1] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/

accumulator program as compared to those in plans without copay accumulator programs.[2] As a result, they can experience disease progression, relapse, and other adverse events, thereby increasing health care utilization.[3]

Millions of American across the country rely on cost-sharing assistance to afford their medications. Such assistance is only helpful if it can be counted toward patients' deductibles or maximum out-out-pockets limits. This is especially problematic during the COVID-19 pandemic when unemployment rates are dramatically increasing every week, and individuals are struggling more than ever to afford their medications. As of September 2020, the national unemployment rate is 7.9, which is almost three times higher than it was in September 2019.[4] Many of these individuals may now rely on marketplace exchange plans with high out-of-pocket costs or may have spouses or partners who have lost their health insurance, thereby reducing their disposable income. Therefore, UHC's AAP could have a detrimental impact on patients, especially during the pandemic.

C. Impact of UHC's AAPs on Providers

UHC's AAP could also have a detrimental impact on health care providers. UHC's provider protocol details a 14-step process that a provider must complete on behalf of his or her patients in order to receive payment for the provider's services rendered. UHC puts the onus on the provider to obtain coupon reimbursement from the manufacturer and to submit that coupon value to UHC. UHC notes that the reimbursement value may trigger a second adjudication of a claim, which may affect the patient's cost share responsibility. It appears that UHC will not reimburse the provider for services until all the steps have been completed.

Not only is this process burdensome and time-consuming, but it could cause significant delays for providers in receiving payment for their services. UHC's communication to providers indicated a 60-day claim adjudication delay. Yet, most states require insurers to pay claims within 30 to 45 days.[5] Such a policy is especially troublesome during the COVID-19 pandemic when many health care providers are struggling to remain open. Many health care practices have had to shut their doors during the pandemic due to state social distancing orders.[6] Additionally, patients' health care utilization has significantly decreased due to both social distancing orders and fear of exposure to COVID-19. As a result, health care providers have had to reduce their administrative staff and have suffered significant financial losses.[7] One recent estimate showed the U.S. health care system facing a 55 to 70 percent decrease in revenue as a result of reduced in-person clinical visits.[8] According to a survey released in September 2020, 42 percent of physicians have had to lay off or furlough staff, and about 10 percent say they will have to close within the next month

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[2] https://www.ajmc.com/view/impact-of-a-copay-accumulator-adjustment-program-on-specialty-drug-adherence
[3] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[4] https://www.bls.gov/news.release/pdf/empsit.pdf
[5] https://www.uphelp.org/pubs/health-care-resolving-billing-problems-and-claim-denials#:~:text=Most%20states%20require%20insurers%20to,your%20provider%20to%20get%20paid.
[6] https://www.washingtonpost.com/outlook/2020/04/24/pandemic-could-put-your-doctor-out-business/?arc404=true
[7] https://www.herald-dispatch.com/business/small-doctor-practices-struggle-to-survive-amid-coronavirus-pandemic/article_f8004973-5d2a-57d8-8257-1e63f34abe6e.html
[8] https://www.washingtonpost.com/outlook/2020/04/24/pandemic-could-put-your-doctor-out-business/?arc404=true

because of financial shortfalls.[9] Without administrative staff, there is no one to complete UHC's 14-step protocol, and with reduced financial reserves, health care providers cannot afford to have their payments delayed.

D. State Consumer Protection Laws

UHC's policy states that it will not apply if it is prohibited by state law. Currently, five states have implemented laws that ban or limit the use of AAPs. At least four of these states (Georgia, Illinois, Virginia, and West Virginia) have implemented laws that do not distinguish between pharmacy benefits and medical benefits, and therefore, would prohibit UHC's AAP.[10]

Additionally, based on the way UHC has set up its protocol, the value of the manufacturers' coupons goes to health care providers to cover the drug cost, which could be construed as implicating many states' anti-kickback laws.[11] Therefore, UHC's protocol has created a catch-22. If health care providers comply with UHC's protocol, they may be subject to criminal penalties, including fines, revocation of their state medical licenses, and even prison for potentially violating state anti-kickback laws.[12] If they choose not to comply with UHC's protocols, then UHC may not

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[9] https://www.herald-dispatch.com/business/small-doctor-practices-struggle-to-survive-amid-coronavirus-pandemic/article_f8004973-5d2a-57d8-8257-1e63f34abe6e.html

[10] http://www.legis.ga.gov/Legislation/20192020/195227.pdf; https://www.ilga.gov/legislation/publicacts/101/PDF/101-0452.pdf; https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+HB2515ER+pdf; http://www.wvlegislature.gov/Bill_Text_HTML/2019_SESSIONS/RS/bills/HB2770%20SUB%20ENR.pdf

[11] See e.g., Alaska Stat. Ann. § 11.46.660(a)(3) (creating criminal liability for a physician soliciting/accepting any benefit for referral of business to the payer); Cal. Bus. & Prof. Code § 650 (creating criminal liability for a state medical professional's offer/delivery/receipt of compensation for referral of health care services); Conn. Gen. Stat. § 53a-161c(a)(2) (creating criminal liability for soliciting/accepting any benefit for referral of goods/services reimbursable under a local, state, or federal health care program); Fla. Stat. Ann. § 456.054(2)-(3) (creating criminal liability for offering/paying or receiving a kickback for referral of patients); Idaho Code Ann. § 41-348(1) (creating civil liability for paying or accepting payments for referral of a client); 844 Ind. Admin Code § 5-2-11 (creating professional liability for a practitioner paying/receiving compensation for referral of a patient); La. Stat. Ann. § 37:1745(B) (creating criminal liability for soliciting/receiving or offering/paying any remuneration for referrals of any health care goods/services); Mass. Gen. Laws ch. 175H, § 3 (creating criminal and civil liability for soliciting/receiving or offering/paying any remuneration for referrals of goods/services reimbursable by any health care insurer); Minn. Stat. Ann. § 147.091(1)(p)(1) (creating civil and professional liability for physicians soliciting/receiving or offering/paying remuneration for referral of patients); Mo. Rev. Stat. § 191.905(2)- (3) (creating criminal and civil liability for soliciting/receiving or offering/paying any remuneration for referral of any health care); N.J. Admin. Code § 13:45J1.3(c) (creating administrative liability for physicians and other healthcare providers accepting "any item of value that does not advance disease or treatment education" from pharmaceutical manufacturers); N.M. Stat. Ann. § 61-6-15 (creating professional liability for offering/delivering or receiving/accepting consideration for referring patients); Ohio Rev. Code Ann. § 3999.22(B) (creating criminal liability for offering/receiving any remuneration for referral of goods/services reimbursable by any health care plan); Okla. Stat. Ann. tit. 63, § 1- 742(A) (creating criminal, civil, and professional liability for paying/accepting anything of value for referral of patients); R.I. Gen. Laws § 5-48.1-3(a)-(b) (creating criminal liability for soliciting/receiving or offering/paying any remuneration for referral of any health care item/service); S.C. Code Ann. § 44-113-60 (creating criminal liability for a health care provider offering/paying or soliciting/receiving any remuneration for referral of patients); Texas Occ. Code Ann. § 102.001(a) (creating criminal liability for soliciting/accepting or offering/paying any remuneration for referral of patients); Utah Code Ann. § 26-20-4 (creating criminal and civil liability for soliciting/receiving or offering/paying any remuneration for referral of goods/services reimbursable under any health care program); Wash. Rev. Code Ann. §§ 19.68.010, 19.68.020 (creating criminal and professional liability for offering/paying or accepting valuable consideration for referral of health care services).

[12] *Id.*

reimburse them for their services, thereby jeopardizing their sustainability. As such, we ask UHC to revoke its AAP policy.

Thank you for considering our position on UHC's AAP. The undersigned organizations would like to schedule a call with you to discuss this issue further. Please contact Stacey Worthy at policy@aimedalliance.org to arrange this call or with any questions you may have.

Sincerely,

Aimed Alliance
Alliance for Patient Access
American Association of Clinical Urologists, Inc.
American Autoimmune Related Diseases Association
American Behcet's Disease Association
American Chronic Pain Association
Bleeding Disorders Advocacy Network
Bleeding Disorders Association of Northeastern New York
Bleeding Disorders Association of the Southern Tier
Bridge the Gap - SYNGAP Education and Research Foundation
CancerABCs
Center for Medicine in the Public Interest
Chronic Care Policy Alliance
Chronic Disease Coalition
Coalition of State Rheumatology Organizations
Community Liver Alliance
CURED Foundation
Digestive Disease National Coalition
Equitas Health
Global Healthy Living Foundation
HealthyWomen
Hemophilia Association of New York
Hemophilia Services Consortium Inc.
Immune Deficiency Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Foundation for Gastrointestinal Disorders
International Pemphigus and Pemphigoid Foundation
Lupus and Allied Diseases Association
Lymphatic Education and Research Network
Mary M. Gooley Treatment Center
Mental Health America of Ohio
Miles for Migraine
National Alopecia Areata Foundation
NephCure Kidney International
New York City Hemophilia Chapter

New York State Bleeding Disorders Coalition
Patient Power
Patients Rising Now
Pompe Alliance
Restless Leg Syndrome Foundation
Rock CF Foundation
Scleroderma Foundation
Spondylitis Association of America
Triage Cancer
The Association of Black Cardiologists
The Cystic Fibrosis Engagement Network
The Coalition for Hemophilia B
The diaTribe Foundation
The Gaucher Community Alliance
The Infusion Access Foundation
the National Alliance of State Prostate Cancer Coalitions
The National Infusion Center Association
The National Organization of Rheumatology Managers
The Ohio Sickle Cell and Health Association
The Ohio State Grange
The Partnership to Advance Cardiovascular Health
The Prostate Conditions Education Council
The Sjögren's Foundation
The U.S. Hereditary Angioedema Association
The Vasculitis Foundation
United Ostomy Associations of America, Inc.
Western New York Blood Care