August 2, 2018

Yada Horace
Insurance Rate Analyst
Alabama Department of Insurance
201 Monroe Street
Montgomery, Alabama 36104

RE: Alabama PY 2020 EHB Benchmark Plan

Dear Ms. Horace:

Thank you for the opportunity to comment on Alabama's proposed EHB Benchmark Plan for plan year 2020. The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals, by advocating, educating, and litigating at the federal and state level.

Truncated Public Comment Process

Federal regulation requires states to provide "reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan."[i] There has not been a reasonable opportunity to comment on Alabama's EHB base benchmark plan (BBP) changes because of the truncated length of the comment period and the lack of access to critical information about the changes made.

First, the timeframe provided for public comment was too short to be reasonable. For the 2020 plan year, states were required to submit their completed EHB BBP proposals to HHS by July 2, 2018. Here, the public notice and comment period was not initiated until July 19, 2018—well after the BBP proposals and supporting documents were due to HHS. There has been no transparency about the application process and timeline until well after the HHS deadline. Additionally, the comment period established by Alabama closes on August 3, 2018. This allows the public only two weeks to review the proposed changes and

provide comments. Two weeks is not a reasonable length of time to allow for meaningful public review and comment. This is not enough time for advocates and stakeholders to thoroughly review the benchmark changes and the implications for consumers. Alabama's comment period should have been a minimum of 30 days.

Second, Alabama did not make available the required supporting documentation for public review, leaving the public without adequate information to provide meaningful input. Federal regulation requires states making changes to their BBP to submit documents to HHS, including:

1. A "document confirming the State's EHB-benchmark plan definition complies with the requirements … of this section, including information on which selection option … the State is using, and whether the State is using another State's EHB-benchmark plan,"
2. "[A]n actuarial certification and an associated actuarial report from an actuary" that affirms the BBP exceeds the typical employer plan floor and does not exceed the generosity ceiling, and
3. A formulary drug list.[ii]

The state has not made available any of this documentation for public review during the comment period. Without access to these documents, especially to the formulary drug list and actuarial analysis, Alabama is depriving the public of the opportunity to review the BBP and provide public comment on the impact of the proposed changes. Without providing this key documentation, Alabama has not provided a reasonable opportunity for public comment.

Alabama's Plan Violates Key Federal EHB Protections

Under the Notice of Benefit and Payment Parameters for 2019 final rule, the EHB prescription drug requirement has not changed. The failure to cover entire classes of drugs violates minimum standards for prescription drug coverage for plans subject to EHB protections. Plans providing EHB must cover at least one drug per class and category under the U.S. Pharmacopeia (USP).[iii] Alabama's proposed changes fall short of that standard. Moreover, the state's proposed changes to its BBP would violate non-discrimination protections under federal law by removing and disproportionately reducing drugs relied on by patients with HIV/AIDS.[iv] HHS has previously observed that plans may have discriminatory benefit designs even if they meet minimum prescription drug coverage standards.[v]

Plan Does Not Further State's Goal of Reducing Opioid Epidemic

One of the main reasons Alabama has stated for making the proposed BBP changes, reducing the opioid epidemic, will not be accomplished by the proposed changes. The proposed changes further limit access to critical opioid overdose prevention and opioid dependence treatment medications, and instead focus on reducing access to opioid medications, which may harm patients with legitimate medical needs for opioid medications, such as cancer patients.

The proposed changes exclude coverage of the opioid reversal agent Naloxone, leaving the Opioid Reversal Agent Class of the USP Anti-Addiction/Substance Abuse Treatment Agents Category empty. Naloxone access is critical to fighting the opioid epidemic. A study by the National Bureau of Economic Research found that increasing access to Naloxone is linked to a nine to eleven percent reduction in opioid-related deaths.[vi] Any benchmark plan aimed at combatting the opioid epidemic should include Naloxone, and since Naloxone is the only drug in its class it must be covered by health plans, but it is notably absent from Alabama's proposed benchmark plan.[vii]

The proposed changes also reduce the drug count for the Class of Opioid Dependence Treatments, while increasing the drug count for the Alcohol Deterrents/Anti-Craving Class. The USP Opioid Dependence Treatments Class includes both Naltrexone and Buprenorphine, but under the proposal, plans would only have to cover one of these two drugs. Access to Medication Assisted Therapy (MAT) has been shown to reduce opioid deaths and to be much more effective in helping those with opioid use disorder overcome their addictions than those without it.[viii] Reducing the availability of opioid dependence treatments will worsen, not improve, the opioid epidemic.

While reducing access to opioids for those who do not need them is an important part of combatting the opioid epidemic, strategies that limit access to pain medication for those that really need it harm patients. Untreated and inadequately treated pain is a serious medical, ethical, and economic concern.[ix] Both chronic and acute pain are highly prevalent in the United States, and are correlated with other negative health conditions including depression and anxiety.[x] In addition to its physical and emotional effects, untreated pain is responsible for hundreds of billions of dollars annually in lost productivity and other costs.[xi]

It is also possible that lack of access to needed opioids may drive some patients to the black market, where they may be exposed to more potent opioids and opioid analogs.[xii] This phenomenon is now well established among some patients prescribed opioids for chronic pain, and it is possible that limiting access to the type of opioids prescribed for those with legitimate acute pain and treatment needs may encourage individuals with acute pain to attempt to access opioids through non-legitimate channels as well.[xiii]

Plan Harms Alabamans by Limiting Access to Key Drugs

The proposed BBP excludes critical drugs. In addition to excluding the Opioid Reversal Agents Class discussed above, the proposed BBP excludes critical drugs including cancer treatment, hepatitis C, mental health treatment, and other drugs.

Cancer treatment is a critical part of health care. In Alabama, 72 people are diagnosed with cancer every day, with 26,150 new cases in 2015 alone.[xiv] Monoclonal Antibody/Antibody Drug Conjugates are important cancer-fighting drugs. They are used alone or in combination with other drugs to fight aggressive forms of cancer, including: metastasized or recurring cervical cancer, colorectal cancer, glioblastoma, nonsquamous non-small cell lung cancer, ovarian and other reproductive organ cancers, and renal cell carcinoma; leukemia; multiple myeloma (bone marrow cancer); neuroblastoma in children; and melanoma that cannot be treated with surgery or has spread to other body parts.[xv] Excluding this class of drugs from Alabama's BBP will leave Alabamans with cancer without access to these life-saving medications. Likewise, Antineoplastic Treatment Adjuncts are an important part of cancer treatment. These drugs are used to prevent deadly side effects from chemotherapy and radiation in cancer patients, and are critical to the survival of many patients undergoing cancer treatment.

The BBP also excludes all treatment for hepatitis C. This is extremely concerning given the fact that Alabama's rates of hepatitis C are above the national average and that reported rates of acute hepatitis C in Alabama increased by 180 percent between 2011 and 2015.[xvi] Hepatitis C is a viral infection that spreads through contaminated blood. If untreated, hepatitis C can cause cirrhosis of the liver and lead to cancer or death.[xvii] Excluding drugs that treat hepatitis C from the state's BBP is irresponsible and will leave large numbers of Alabamans without needed treatment.

The USP Hemostasis Agents Class is also improperly excluded from the drug list. These drugs are used for those with high-risk bleeding conditions to control bleeding after surgery or an injury, during heavy nosebleeds, or heavy menstrual bleeding.[xviii] These drugs are critical for individuals with bleeding disorders and should not be excluded from the BBP drug list.

Benzodiazepines are also a USP class with no drugs included on the drug list. Benzodiazepines are important for treating seizures, alcohol withdrawal, panic attacks, insomnia, and generalized anxiety disorder.[xix] These drugs are essential tools in treating patients in Alabama, and should not be excluded from the drug list.

Progesterone Agonists/Antagonists have also been excluded. This category encompasses ulipristal, which is essential to treatment of uterine fibroids and should be included in the

prescription drug list. It may also be used as an emergency contraceptive and is thus required to be included in the EHB BBP as a preventive service.[xx]

Passive Immunizing Agents are also excluded. These drugs are used to provide protection against certain viral infections for individuals who have not been vaccinated or haven't had the infection before, to protect those with compromised immune systems, and to prevent the body from rejecting organ transplants.[xxi] The USP Class of Pulmonary Fibrosis Agents is also not included. These drugs are used to treat idiopathic pulmonary fibrosis, which is a lung disease that can lead to collapsed lung, blood clots in the lungs, lung cancer, respiratory failure, pulmonary hypertension, and heart failure.[xxii] These drugs are critical to patient care and should not be excluded.

The Vaccine Class of the Immunological Agents Category is notably missing from the proposed drug list provided.[xxiii] This drug class includes a wide range of vaccines such as Tetanus and Diphtheria; Measles, Mumps, and Rubella; Yellow Fever; and Human Papillomavirus. These and other excluded vaccines are critical to protecting Alabamans from horrible diseases like measles, mumps, HPV, meningitis, viral encephalitis, hepatitis A, rabies, rotavirus, and polio—to name a few. There is nothing to require coverage of vaccines outside of the essential health benefits protections. Excluding this class of drugs from the benchmark plan may prevent unvaccinated Alabamans from getting important vaccines and put the public at risk of an avoidable infectious disease outbreak.

Finally, the prescription drug list excludes the entire USP Category of Electrolytes/ Minerals/ Metals/ Vitamins. This category of drugs is incredibly diverse and used to treat countless different diseases and health problems. For example, Deferasirox is in this category and is used to treat high levels of iron in the body in people who have had frequent blood transfusions, which are often needed by those with certain blood diseases like sickle cell disease and anemia.[xxiv] Excluding this category from the prescription drug list leaves many Alabamans without access to needed drugs.

The proposed drug list also reduces the drug count in a number of USP Categories and Classes that are essential to the health care of individuals with HIV, genetic disorders, diabetes, seizure disorders, mental illness, cancer, heart disease, and autoimmune disorders, among other conditions. These reductions will limit the treatment options that physicians can use and will ultimately harm Alabamans, particularly those who are most vulnerable and in need of consistent and appropriate health care access.

Conclusion

For the aforementioned reasons, we urge Alabama's Department of Insurance to maintain coverage of the prescription drugs that consumers need and not make the proposed changes to the EHB benchmark. Thank you for your attention to our comments. If you have

any questions or need any further information, please contact Hayley Penan, Staff Attorney (penan@healthlaw.org; 310-736-1652).

Sincerely,

Hayley Penan, JD, MPH
Staff Attorney
National Health Law Program (NHeLP)

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[i] 45 C.F.R. § 156.111 (2018).
[ii] *Id.*
[iii] *See* 45 C.F.R. §156.122.
[iv] 42 U.S.C. § 18116; 45 C.F.R. § 156.110(d); 45 C.F.R. § 156.125; 45 C.F.R. § 156200(e).
[v] Centers for Medicare & Medicaid Services, *2017 Letter to Issuers in the Federally-facilitated Marketplaces*, HHS (Feb. 29, 2016), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf; Centers for Medicare & Medicaid Services, *FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces*, HHS (Feb. 20, 2015), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf.
[vi] Daniel Rees et al., *With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths*, NAT'L BUR. ECON. RES. (Feb. 2017), http://www.nber.org/papers/w23171?utm_campaign=ntw&utm_medium=email&utm_source=ntw.
[vii] 45 C.F.R. § 156.122.
[viii] Kate Sheridan, *How effective is medication-assisted treatment for addiction? Here's the science*, STAT NEWS (May 16, 2017), https://www.statnews.com/2017/05/15/medication-assisted-treatment-what-we-know/.
[ix] Deyo, Mirza & Martin, *Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002*, 31 SPINE 2724-27 (2006); Institute of Medicine (U.S.). Committee on Advancing Pain Research Care and Education, *Relieving pain in America : a blueprint for transforming prevention, care, education, and research* (2011); Kehlet, Jensen & Woolf, *Persistent postsurgical pain: risk factors and prevention, 367* LANCET 1618-25 (2006); Verhaak et al., *Prevalence of chronic benign pain disorder among adults: a review of the literature*, 77 PAIN 231-39 (1998).
[x] Bair et al., *Prevalence of pain and association with quality of life, depression and glycaemic control in patients with diabetes,* 27 DIABETIC MED. 578-84 (2010); McWilliams, Goodwin & Cox, *Depression and anxiety associated with three pain conditions: results from a nationally representative sample,* 111 PAIN 77-83 (2004); Tsang et al., *Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders*, 9 J. PAIN 883-91 (2008).
[xi] Dagenais, Caro & Haldeman, *A systematic review of low back pain cost of illness studies in the United States and internationally, 8* SPINE J. 8-20 (2008).

[xii] Barnett et al., *Coupling Policymaking with Evaluation - The Case of the Opioid Crisis*, 377 N. ENG. J. MED. 2306-09 (2017).
[xiii] Dasgupta et al., *Observed Transition From Opioid Analgesic Deaths Toward Heroin*, 145 DRUG ALCOHOL DEPEND. 145, 238-41 (2014).
[xiv] Alabama Cancer Facts & Figures 2015, https://www.alabamapublichealth.gov/ascr/assets/FactsFigures2015.pdf.
[xv] This is just a sampling of the multitude of uses of this class of cancer fighting drugs.
[xvi] Susan Scutti, *New hepatitis C infections triple due to opioid epidemic*, CNN (May 11, 2017), https://www.cnn.com/2017/05/11/health/hepatitis-c-rates-cdc-study/index.html; *Alabama – State Health Profile*, CDC, https://www.cdc.gov/nchhstp/stateprofiles/pdf/alabama_profile.pdf.
[xvii] *Hepatitis C,* MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/hepatitis-c/symptoms-causes/syc-20354278.
[xviii] *See, e.g.*, *tranexamic acid 500 milligram tablet - oral, Cyklokapron*, MEDICINENET, https://www.medicinenet.com/tranexamic_acid-oral/article.htm.
[xix] Joseph Nordqvist, *The benefits and risks of benzodiazepines*, MED. NEWS TODAY (Jan. 5, 2018), https://www.medicalnewstoday.com/articles/262809.php.
[xx] Section 2713; *Women's Preventive Services Guidelines*, HEALTH RESOURCES & SERVICES ADMINISTRATION, https://www.hrsa.gov/womensguidelines2016/index.html (last visited Sept. 14, 2017).
[xxi] *See, e.g., Anti-Thymocyte Globulin*, EVERYDAY HEALTH, https://www.everydayhealth.com/drugs/anti-thymocyte-globulin-rabbit; *immune globulin - intramuscular, Baygam, Gamastan, Gammar*, MEDICINENET, https://www.medicinenet.com/immune_globulin-intramuscular/article.htm.
[xxii] *Idiopathic Pulmonary Fibrosis*, HHS, https://www.nhlbi.nih.gov/health-topics/idiopathic-pulmonary-fibrosis.
[xxiii] This is in contrast to the other classes of drugs discussed, which are included in the drug list provided, bot for which there is a drug count of zero for that category or class.
[xxiv] *Deferasirox Tablet*, WEBMD, https://www.webmd.com/drugs/2/drug-94592-1694/deferasirox-oral/deferasirox-oral/details.