via electronic submission

August 3, 2018

Jim L. Ridling
Commissioner
Alabama Department of Insurance
201 Monroe Street
Suite 502
Montgomery, AL 36104

Re: ACS CAN's Comments on Alabama PY2020 EHB Benchmark Plan Revisions

Dear Commissioner Ridling:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Alabama Department of Insurance's Plan Year 2020 Essential Health Benefits (EHB) Plan Revisions. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN supports a robust marketplace from which consumers can choose a health plan – including prescription drug coverage – that best meets their needs. In the United States, there are more than 1.7 million Americans who will be diagnosed with cancer this year.[1] An additional 15.5 million Americans are living with a history of cancer.[2] In Alabama, an estimated 27,830 residents are expected to be diagnosed with cancer this year[3] and another 223,990 are cancer survivors.[4] For these Americans access to comprehensive health insurance is a matter of life or death.

ACS CAN has serious concerns about how this proposal will impact these cancer patients' and survivors' access to the drugs they need to treat their cancer, address side effects like pain, and prevent cancer recurrence. We are also troubled that the process by which the Alabama Department of Insurance (the Department) is considering these changes is not open and transparent, and will set a bad precedent for other states. We urge the Department to

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[1] American Cancer Society. Cancer Facts & Figures: 2018. Atlanta: American Cancer Society, 2018.
[2] Id.
[3] Id.
[4] American Cancer Society. Cancer Treatment & Survivorship: Facts & Figures 2016-2017. Atlanta: American Cancer Society, 2016.

withdraw this proposal and work with patient groups to ensure patient access is not jeopardized.

The Proposal Reduces Patient Access to Pain Treatment – Including Opioid Alternatives

The Department proposes to change its benchmark for the EHB prescription drugs category by cutting the number of drugs required to be covered by qualified health plans (QHPs) in the state. The Department asks for comments on a list of drug counts,[5] and proposes to cut the number of required drugs in some, but not all, categories and classes of drugs. The Department states that it is proposing these changes to "reduce premiums and address the opioid crisis."[6]

ASC CAN recognizes the current public health emergency caused by the inappropriate use of prescription opioids and the harms associated with such use. As a nation, we must take steps to address the issue in Alabama and nationwide, and we welcome the opportunity to represent the voices of cancer patients and survivors in such efforts. At the same time, it is important to keep in mind that many cancer patients and survivors legitimately need access to opioids as part of their treatment.

Pain is one of the most feared symptoms for cancer patients and survivors - nearly 60 percent of patients in active treatment and 30 percent of patients who have completed treatment experience pain.[7] Pain can be caused by the cancer itself, for instance when tumors interfere with normal body function. Pain can also be caused by cancer treatments. For example, research has concluded that about one-quarter of women who have had breast cancer surgery have significant and persistent breast pain six months after the procedure.[8] Integrative pain care that includes non-drug therapies along with medications is encouraged to keep patient pain under control. While not the only tool (and not the only type of pain medication), opioids are recognized as mainstays of treatment for moderate to severe cancer pain and can be a beneficial treatment for managing serious, persistent pain for patients being actively treated for cancer and for cancer survivors.

ACS CAN supports policies that take a reasonable, balanced approach to addressing the opioid addiction epidemic and its associated risks, without harming patients who are using the medications appropriately to treat their pain. Unfortunately, we do not believe that this proposal strikes the appropriate balance.

National polling conducted by ACS CAN and the Patient Quality of Life Coalition shows that cancer patients and survivors are already having problems getting insurance to cover their opioid pain medications: 30 percent of the cancer patients and survivors responding to the

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[5] Alabama Department of Insurance. 2017 Prescription Drug EHB-Benchmark Plan Benefit Drug Count. July 19, 2018. http://www.aldoi.gov/Legal/2017%20EHB%20Benchmark%20Drug%20Category%20Comparison.pdf
[6] Alabama Department of Insurance. EHB-Benchmark Plan Revisions. July 19, 2018. http://www.aldoi.gov/currentnewsitem.aspx?ID=1008
[7] Institute of Medicine. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research. 2011. National Academy of Sciences.
[8] Miaskowski C, Cooper B, Paul SM, et al. Identification of Patient Subgroups and Risk Factors for Persistent Breast Pain Following Breast Cancer Surgery. J Pain 2012; 13(12) pp 1172-1187.

survey reported being unable to get their opioid prescription pain medication because insurance would not cover it. This number is up 19 percentage points since we asked cancer patients and survivors the same question in 2016.[9] ACS CAN is concerned that the proposed cuts will exacerbate this already growing problem in Alabama.

Furthermore, drastically cutting coverage of all opioid treatments is not the best way to address opioid misuse by a segment of the population. Those with serious illness and nearing the end-of-life often need access to these drugs for legitimate pain and other symptom relief. ACS CAN supports policy solutions that address the legitimate need that some patients have for opioids, while keeping them out of the hands of individuals who are abusing or misusing these drugs. These policy solutions include expanding the use and capabilities of prescription drug monitoring programs; increasing provider training in proper, integrative pain management; and finding ways to identify patients who are or are at risk of misusing opioids and targeting treatment interventions to them. ACS CAN does not believe the proposed cuts in drug coverage are well-tailored to deliver the intended outcome, and we welcome the opportunity to discuss other reasonable and balanced policy solutions with policymakers in Alabama.

The following chart highlights selected rows of the Department's proposed drug list related to pain management or opioid use disorder:

[9] Public Opinion Strategies, for ACS CAN and Patient Quality of Life Coalition. Key Findings Summary: Opioid Access Research Project. June 14, 2018.
https://www.acscan.org/sites/default/files/ACS%20CAN%20PQLC%20Opioid%20Research%20Project%20Key%20Findings%20Summary%20Memo%20FINAL.pdf

ID	Category	Class	Current Rx Count	Proposed Rx Count	Difference
[Opioid Pain Treatments]					
2	Analgesics	Opioid Analgesics, Long-acting	11	4	-7
3	Analgesics	Opioid Analgesics, Short-acting	14	7	-7
[Non-Opioid Pain Treatments][10]					
1	Analgesics	Nonsteroidal Anti-inflammatory Drugs	20	13	-7
35	Anti-inflammatory Agents	Nonsteroidal Anti-inflammatory Drugs	20	13	-7
36	Antimigraine Agents	Ergot Alkaloids	2	1	-1
37	Antimigraine Agents	Prophylactic	3	2	-1
38	Antimigraine Agents	Serotonin (5-HT)/1d Receptor Agonists	7	4	-3
108	Central Nervous System Agents	Central Nervous System, Other	10	5	-5
109	Central Nervous System Agents	Fibromyalgia Agents	3	1	-2
[Treatments for Opioid Use Disorder]					
6	Anti-Addiction/Substance Abuse Treatment Agents	Opioid Dependence Treatments	2	1	-1
7	Anti-Addiction/Substance Abuse Treatment Agents	Opioid Reversal Agents	0	0	0

[10] This list of categories and classes containing drugs used for pain treatment is not exhaustive of all drugs used to treat pain.

As the chart shows, the proposed cuts reach farther than just the opioid categories. The Department proposes cutting the number of required drugs in multiple other categories and classes related to pain management and treatment of opioid dependence.

ACS CAN questions whether these cuts would actually accomplish the Department's stated intention to address the opioid epidemic. At a time when many policymakers and medical professionals are discussing ways to increase the use of non-opioid pain treatments to stop the opioid epidemic, the Department proposes to drastically cut the number of non-opioid pain medications QHPs are required to cover. Even more surprisingly, the Department proposes to cut the number of opioid dependence treatments it requires to be covered; and according to the chart, the benchmark has never included – and still does not include – opioid reversal agents. This is a category of drugs that includes Naloxone, which the U.S. Surgeon General has recently advised many individuals carry on-hand to prevent opioid overdoses.[11]

ACS CAN believes these proposed cuts are too restrictive and will severely limit patient access to pain treatment, including non-opioid pain treatment. Poorly managed pain in seriously ill patients can contribute to decreased productivity, poorer quality of life, increased health care utilization, and increased mortality.[12] We believe these cuts will harm cancer patients and survivors in Alabama, and we urge the Department to withdraw these proposed cuts.

The Proposal Reduces Access to Treatments for Cancer and Other Serious Illnesses

The Department's rationale for reducing the number of drugs available is to address the opioid crisis. Yet, as noted previously, the proposed drug list reduces the number of drugs required to be covered in many other drug categories and classes. These include cuts to five classes of antineoplastics, the drugs used to treat cancer. The proposal also halves the number of required drugs in the emetogenic therapy adjuncts class, which is the class that includes supportive care drugs patients receive to reduce nausea during chemotherapy.

Drug therapies play an integral role in cancer treatment. Advances in research have improved our understanding of cancer at the molecular level – leading to the development of more precise detection and diagnostic tools and corresponding therapies that are able to more specifically attack cancer. Over the course of the last few years there has been a remarkable increase in the number of new cancer drug therapies. In 2017, 15 out of the 45 new therapies approved by the Food and Drug Administration (FDA) were for cancer.[13] By reducing the minimum number of drugs to be covered within these classes, the Department is making it harder for consumers to access these new treatments when they become available.

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[11] U.S. Department of Health and Human Services. Surgeon General Releases Advisory on Naloxone, an Opioid Overdose-Reversing Drug. April 5, 2018. https://www.hhs.gov/about/news/2018/04/05/surgeon-general-releases-advisory-on-naloxone-an-opioid-overdose-reversing-drug.html.

[12] Eds. Chai E, Meier DE, Morris J, and Goldhirsch S. Management of pain in older adults. *Geriatric Palliative Care.* New York: Oxford University Press, 2014. 159-169.

[13] HBM Report. Trends in US New Drug Approvals. January 2018. http://www.hbmpartners.com/media/docs/industry-reports/HBM-Partners-Report-Trends-in-FDA-New-DrugApprovals-2008-2017.

Some patients may have to try different drugs within one class before it is possible to determine the most optimal drug for their condition. Patients may also have co-morbidities requiring very nuanced treatment regimens. Additionally, many of these prescription drugs are not necessarily therapeutically equivalent with products within the same class – making it vital that all the drugs are covered. Not only do the drugs within the antineoplastics category vary widely, but variation exists within the classes. For example, the class of tyrosine kinase inhibitors has been developed to treat cancer, but each drug within this class may target a different mutation that is relevant to a small subcategory of patients with a given disease. This targeting means that limiting coverage within this category would necessarily leave out many unique drugs that would treat distinct cancers.

In other words, allowing plans to choose a limited number of drugs to cover in the antineoplastics category allows these plans to potentially discriminate, picking and choosing between cancer types – i.e., choosing to cover treatments for lung cancer over breast cancer. Furthermore, it also allows plans to pick and choose within those cancer types – i.e., choosing to cover treatment for lung cancer patients with a particular gene mutation over patients with a different mutation. As a result, individuals with certain cancers may be unable to find a plan that covers the drugs they need to successfully treat their condition.

For these reasons, ACS CAN has serious concerns with any proposal that allows plans to not cover a significant number of cancer drugs. Both cancer patients and survivors rely on drug therapies to treat their disease and prevent recurrence. As more innovative therapies become available, we need to make sure that patients who are likely to benefit from these advances can access them so that we can achieve the national goal of eliminating death and suffering from cancer.

The Department also proposes cuts to many other drug categories and classes, including large cuts to drug categories that treat lung disease, cardiovascular disease (CVD), diabetes and depression. These cuts are concerning because many cancer patients and survivors have additional health problems or comorbidities. For example CVD is the most common comorbidity with lung cancer,[14] and female breast cancer survivors have heightened risk of dying from CVD.[15] Some of these comorbidities are caused by cancer treatments, and others are causally unrelated. Regardless, cutting coverage of drugs that treat common comorbidities will negatively impact cancer patients and survivors, who are already paying high costs for drug and other treatments to cure their cancer or prevent its recurrence.

Cutting coverage of cancer or other drugs does not reduce the need for these drugs. The Department's proposed cuts will likely not eliminate the costs of these drugs from the healthcare system – instead ACS CAN is concerned that the proposal will shift costs in two

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[14] Kravchenko, J., Berry, M., Arbeev, K., Lyerly, H. K., Yashin, A., & Akushevich, I. Cardiovascular comorbidities and survival of lung cancer patients: Medicare data based analysis. 2015. *Lung Cancer (Amsterdam, Netherlands)*, *88*(1), 85–93. http://doi.org/10.1016/j.lungcan.2015.01.006.

[15] Bradshaw, P. T., Stevens, J., Khankari, N., Teitelbaum, S. L., Neugut, A. I., & Gammon, M. D. Cardiovascular Disease Mortality Among Breast Cancer Survivors. 2016. *Epidemiology (Cambridge, Mass.)*, *27*(1), 6–13. http://doi.org/10.1097/EDE.0000000000000394.

ways: 1) patients who need drugs that are no longer covered will have to pay the full price out-of-pocket for them, thus shifting costs onto the consumer; and 2) patients who need drugs that are no longer covered and cannot afford their full price out-of-pocket may go without – thus worsening health outcomes and potentially requiring more healthcare services in other areas, like emergency rooms, hospitals and doctor's offices.

Lastly, reducing the robustness of the prescription drug benchmark makes it easier for QHPs in Alabama to design their formularies in such a way as to discourage patients with certain conditions from enrolling in their plan. This is a back-door method of discriminating against patients with pre-existing conditions, and limits choices for cancer patients and others with serious and chronic disease. It also can segment the insurance market and drive up premiums for patients who need to enroll in plans with more comprehensive coverage.

Additional Transparency is Needed

U.S. Department of Health and Human Services (HHS) regulation establishes the process and rules by which states select their EHB benchmark plan and make changes to it. The most recent Notice of Benefit and Payment Parameters final rule[16] gives states more flexibility in this process and in the plans they can select. However, the rule requires the state to notify HHS by July 2, 2018 of its submission of a plan year 2020 EHB benchmark plan. The rule also requires states to provide "reasonable public notice and an opportunity for public comment on the state's selection of an EHB-benchmark plan."[17]

We note that the notice of these proposed changes to the Alabama EHB benchmark was posted on July 19, 2018, which is 17 days past the stated deadline for HHS notification although it is unclear from the available material whether Alabama received an extension on this deadline. Additionally, comments on the proposal are due by August 3, 2018. This allows a public comment period lasting only 11 business days. This is not an adequate or reasonable amount of time for stakeholders to process and comment on such significant and impactful changes to the state's EHB benchmark.

Federal rules also require the state to provide to the Centers for Medicare and Medicaid Services additional documentation, including an actuarial certification and report, if the state intends to change its EHB benchmark.[18] No such information was made available to the public as part of this comment process.

Additionally, the Department has not provided nearly enough information in its public notice to fully evaluate the proposal and its impacts on patients. We note that the public comment notice consists of 2 paragraphs of text and the list of drug categories, classes and counts. The text of the notice only provides one sentence concerning the reasoning for the Department's

[16] U.S. Department of Health and Human Services. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019. Apr. 17, 2018. 74 Fed. Reg. 16903.
[17] 45 C.F.R. § 156.111(c).
[18] See U.S. Department of Health and Human Services. Information on Essential Health Benefits (EHB) Benchmark Plans. Process for Plan Year 2020 EHB-Benchmark Plan Selection. Accessed July 31, 2018. https://www.cms.gov/cciio/resources/data-resources/ehb.html

proposal and does not contain any explanation of the Department's process in determining these cuts.

This raises several questions: Are the proposed new drug counts based on an existing plan? Are there reasons the Department proposed cuts to certain categories and classes, but not others? Did the Department consider drugs in the drug development pipeline, and how these counts will impact patient coverage of new drugs when they are released? Do these changes affect the actuarial value of the state's EHB plans? Does the Department expect these changes to decrease premiums, and if so, by how much? The public notice does not provide answers to these questions, and stakeholders have no opportunity to ask these questions. We are not aware of any public hearings scheduled on this proposal.

The Proposal Could Harm Patients in Other States

The latest rules for states making changes to their EHB benchmarks[19] allows a state to adopt another state's benchmark plan as its own. ACS CAN is seriously concerned that if this proposal is implemented in Alabama, other states may adopt Alabama's prescription drug requirements as their own in future years. This would cause a "race to the bottom" when it comes to drug coverage requirements, and cancer patients and survivors in other states would see the same problems as those in Alabama articulated above.

Conclusion

For all these reasons, ACS CAN strongly urges the Department to withdraw its proposal and work with patient groups to address concerns about patient access to treatment and transparency issues. On behalf of ACS CAN, we thank you for the opportunity to comment on the proposed PY2020 EHB Benchmark Provisions. If you have any questions, please feel free to contact me or have your staff contact Jennifer Singleterry at Jennifer.Singleterry@cancer.org or 202-285-3233.

Sincerely,

Kirsten Sloan
Vice President, Public Policy
American Cancer Society Cancer Action Network

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[19] 45 C.F.R. § 156.111.