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Interim Deputy Medicaid Director Dana Hittle  
500 Summer St. NE, E65  
Salem, OR 97301

Submitted via email to: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Interim Deputy Director Hittle:

On behalf of the Dravet Syndrome Foundation, I am writing in regards to the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). There are 42,900 people with epilepsy in Oregon and about one-third of people with epilepsy rely on Medicaid for health coverage – so this waiver proposal and its implications are of utmost importance. We appreciate the focus on equitable access to healthcare in this waiver. We support Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over.

Unfortunately, this waiver also contains multiple proposals that would undermine access to care and needed medications for people with epilepsy. We are very concerned with the new proposed closed formulary for adults, as well as Oregon's proposals to continue the waiver of retroactive eligibility, continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one, and continue to use of a Prioritized List of services that relies, in part, on a quality-adjusted life year.

The Dravet Syndrome Foundation (DSF) represents individuals living with Dravet syndrome and their families. Dravet syndrome affects approximately 1:15,700 individuals. DSF supports individuals and families navigating life with Dravet syndrome through research funding, advocacy, educational activities, and direct support services. Dravet syndrome is a catastrophic disease that onsets with prolonged, medication-resistant seizures in the first year of life and progresses with an accumulating burden of comorbid conditions including developmental delays, motor impairment, sleep disturbances, and behavioral disruptions, among others. In addition to these disease-specific efforts, DSF represents and advocates for all individuals living with epilepsy through collaborations with the Rare Epilepsy Network, the Epilepsy Leadership Council, the Epilepsy Foundation, the Seizure Action Plan Coalition and the Epilepsy Learning Healthcare System. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, and people living with epilepsy must have meaningful and timely access to physician-directed, person-centered care, to avoid breakthrough seizures and related complications and costs. We outline our specific thoughts and concerns about this proposal below, modified from a statement originally drafted by our partners at the Epilepsy Foundation.

### ***Support Continuous Eligibility***

We support the request for continuous enrollment for children under age six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent people from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage. Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits. Continuous access to care is especially important for people with epilepsy, where even one missed dose of medication can lead to significant complications, including death.<sup>1</sup>

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<sup>1</sup> Faught E, Duh MS, Weiner JR, Guérin A, Cunnington MC. Nonadherence to antiepileptic drugs and increased mortality: findings from the RANSOM Study. *Neurology*. 2008;71(20):1572.



### ***Oppose Closed Formulary***

We are strongly opposed to the proposal to transition to a closed formulary for adults. For the majority of individuals living with epilepsy, anti-seizure medications are the most common and cost-effective treatment for controlling and/or reducing seizures, and they must have meaningful and timely access to physician-directed and person-centered care. There is no “one size fits all” treatment option for

epilepsy, and the response to medications can be different for each person. For example, many of the most commonly utilized medications to treat seizures are contraindicated for individuals with Dravet syndrome and can actually worsen seizures and cognitive outcomes. Individuals with Dravet syndrome are generally on several (3 or more) different anti-seizure medications and will often need to add or make changes to anti-seizure medication regimens throughout their lifetime, including in adulthood. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. To change, limit, or deny access to the prescribed, most effective medications could be extremely dangerous.

Oregon proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs, subject to certain conditions and exclusions, if the manufacturer of such drugs has signed an agreement to pay rebates. Under current law, Oregon can already impose preferred drug lists that require prior authorization before a prescription drug may be covered under Medicaid and use the preferred drug list to negotiate additional rebates with manufacturers. Except for certain classes of drugs that states may exclude, states are barred from imposing fully “closed” formularies under which drugs cannot be covered under any circumstance.

Oregon’s proposal would allow the state to exclude FDA-approved drugs entirely. The state could offer **just one drug per therapeutic class**, which is wholly unacceptable, detrimental, and dangerous to people living with epilepsy and seizures. Oregon’s proposal closely resembles a 2017 Massachusetts proposal to establish a closed formulary in its Medicaid program – which CMS rightly rejected in 2018<sup>2</sup> – and a Tennessee proposal currently under review by CMS that we strongly oppose.<sup>3</sup> Oregon’s proposal is even more restrictive than what Tennessee proposed: Tennessee’s closed formulary would have included protections for epilepsy medications and other classes, Oregon’s proposal has no such protections.

The proposed closed formulary would cover as little as one medication per therapeutic class. This means that only one epilepsy medication could be covered for all adults in Medicaid. As noted above, epilepsy medications are not interchangeable and there is no one treatment that works best for everyone with seizures. For example, many commonly utilized medications for seizure control are mechanistically contraindicated for Dravet syndrome and can exacerbate seizure activity and worsen long-term outcomes. Furthermore, the response to medications, including effectiveness at controlling seizures and side effects, can be different for each person, even those with a shared diagnosis. Even anti-seizure medication specifically indicated for the treatment of seizures in Dravet syndrome can have differential effectiveness from patient to patient, necessitating an individualized approach to medication selection for each patient. Impeding or delaying access to the prescribed, most effective epilepsy medications increases the likelihood of breakthrough seizures and related complications including injury, disability or even death. Further, many people with epilepsy need to take more than one anti-seizure medication to gain or approach seizure control; as mentioned above, in Dravet syndrome, it is common for patients to utilize three or more anti-seizure medications to reach acceptable levels of seizure control. The waiver does not appear to include any kind of appeals or exceptions process for people in various situations such as already being stable on a medication, or those who need to take more than one medication at a time to treat their condition. Physicians and people with epilepsy work together to determine the appropriate regimen, based on the type of seizure, seizure frequency, age, gender, other health conditions, other medications, and side effects.

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<sup>2</sup> Centers for Medicare & Medicaid Services, MassHealth Demonstration Amendment Approval, June 27, 2018, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf>.

<sup>3</sup> Health Partners Comments on Special Terms & Conditions for TennCare III. September 9, 2021. [https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-\(final\).pdf](https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-(final).pdf)



Oregon's proposal could result in sudden loss of coverage for anti-seizure medications that beneficiaries are currently taking. Most anti-seizure medications need to be titrated to an individualized dose, and that dose needs to be determined to be effective in a specific individual. When switching medications, anti-seizure medications must be titrated down to safely wean the individual off. This process can take months. The formulary change could have significant negative impact on people with epilepsy who are currently stable on their medications. People who are seizure free have been found to have a 16.7% rate of seizure recurrence after a medication switch, compared to 2.8% among those remaining on the same drug.<sup>4</sup>

Oregon states that it seeks to implement a "commercial-style" and points to the rising restrictions in the commercial market. However, those restrictions are not without consequences. One study found formulary restrictions resulted in an average of 6.9 days of delay and 35% lower likelihood of successful dispensing, compared to claims that did not meet with formulary restrictions.<sup>5</sup> Oregon also points to restrictions allowed by Medicare Part D plans without recognizing that Part D plans are required to cover all or substantially all drugs in classes of clinical concern, often known as the "Six Protected Classes," which includes anti-convulsant medications. Oregon includes no such protections for these vulnerable populations in their proposal.

The waiver application makes clear that Oregon's intent in seeking a closed formulary is to reduce costs. However, on top of the dangerous possible consequences to health and life detailed above, restricting access to epilepsy medications will not achieve savings. People with epilepsy whose medications are switched have a high chance of seizure recurrence and in turn, higher medical costs. A review of studies has shown that the direct, epilepsy-related medical costs associated with uncontrolled epilepsy are 2 to 10 times higher than costs associated with controlled epilepsy.<sup>6</sup> There are 42,900 people with epilepsy in Oregon. Oregon's closed formulary could force many of them to switch medications, resulting in costly and avoidable ambulance services, emergency room visits, injuries, and hospital stays.

Additionally, Oregon proposes to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval processes. This will also harm patients by restricting access to novel and lifesaving therapies. To date, no epilepsy medications have been approved through accelerated approval, but we are concerned that this proposal could extend to any other new treatment which the state deems ineffective, despite the decisions of the FDA. States should not be in the position of determining the safety and efficacy of medications; that role is reserved for the FDA.

All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life. We request that the Oregon Health Program remove these requests and

provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that they and their providers have determined are best for them.

### ***Oppose Continuing to Eliminate Retroactive Coverage***

We are concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding those eligible through a disability pathway. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common for people to be unaware that they are eligible for Medicaid until a medical crisis. Retroactive eligibility allows people with epilepsy who have either been newly diagnosed or need a new treatment regime to begin treatment right away, avoiding delays in lifesaving care and without the burden of medical debt while they work on eligibility paperwork. This is particularly important for some groups that experience health disparities, such as African Americans, who are more likely to be diagnosed with epilepsy in an emergency room.<sup>7</sup> Retroactive eligibility

<sup>4</sup> Seizure outcome after switching antiepileptic drugs: A matched, prospective study. *Epilepsia*, 57(8), 1294–1300. <https://doi.org/10.1111/epi.13435>

<sup>5</sup> Mehta, D., Davis, M., Epstein, A.J. et al. (2020). Impact of formulary restrictions on antiepileptic drug dispensation outcomes. *Neurol Ther* 9, 505–519. <https://doi.org/10.1007/s40120-020-00195-3>.

<sup>6</sup> Begley, Charles E. & Durgin, Tracy L. (2015). The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates. *Epilepsia*, 56(9), 1376-1387. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.

<sup>7</sup> Epilepsy Foundation, "Epilepsy and African Americans." Available at: <https://www.epilepsy.com/living-epilepsy/epilepsy-and/african-americans>



also helps low-income residents avoid medical debt they cannot afford to take on. Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>8</sup> Without retroactive eligibility, people with epilepsy who are eligible for Medicaid could face substantial costs and delays at their doctor's office or pharmacy.

People with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>9</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. We oppose the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries. Retroactive coverage is a critical part of Medicaid's safety net.

### ***Oppose Prioritized List and Use of Quality Adjusted Life Years***

We are concerned about the use of a Prioritized List to determine coverage and access to treatments in Oregon, including the use of the quality adjusted life year (QALY) in determining coverage and access.

QALYs are typically developed by surveying the general public about their preferences for health states. Significant evidence exists that the general public has strong anti-disability bias, up to and including withholding health care on the basis of disability. These societal preferences were on display during the COVID-19 pandemic, when many hospital Crisis Standards of Care included plans to discriminate on the basis of disability and de-prioritize care for people with disabilities.<sup>10</sup> Fortunately, HHS OCR issued guidance early in the pandemic stating, "Persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities or age."<sup>11</sup> Disability advocacy organizations filed complaints to change initial crisis standards of care, including in Oregon.<sup>12,13</sup>

In 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage. This application was denied by the U.S. Department of Health and Human Services as violating the Americans with Disabilities Act (ADA).<sup>14</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance.

According to Disability Rights Oregon, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Oregon's Prioritized list is created by the Health Evidence Review Commission (HERC). HERC relies on QALYs for some of its reviews of clinical and cost effectiveness to determine placement on the prioritized list. For example, QALYs are cited in the recent reports: Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease;<sup>15</sup> Multisector Intervention Report: Multicomponent

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<sup>8</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>9</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>10</sup> Center for Public Representation, "COVID-19 Medical Rationing & Facility Visitation Policies." Available at: <https://www.centerforpublicrep.org/covid-19-medical-rationing/>

<sup>11</sup> U.S. Department of Health and Human Services Office for Civil Rights. Bulletin: Civil Rights, HIPAA, and Coronavirus Disease 2019. March 28, 2020. Available at: <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>

<sup>12</sup> Disability Rights Oregon. Press Release. May 8, 2020. Available at: <https://www.centerforpublicrep.org/wp-content/uploads/2020-05-08-Release-on-OCR-Letter.pdf>

<sup>13</sup> Oregon Health Authority. Principles in Promoting Health Equity During Resource Constrained Events. December 7, 2020. Available at: <https://sharedsystems.dhsosha.state.or.us/DHSForms/Served/le3513.pdf>

<sup>14</sup> Sullivan, Louis W., Oregon Health Plan Is Unfair to the Disabled, The New York Times. August 13, 1992. Available at: <https://www.nytimes.com/1992/09/01/opinion/1-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>15</sup> Oregon HERC. Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease. November 14, 2019. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CHW-Multisector-Report-Final.pdf>



Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer;<sup>16</sup> and Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring.<sup>17</sup>

We are concerned with the existence of the Prioritized List at all, and further concerned about the use of QALYs to determine who gets care. QALYs discriminate against people with disabilities by devaluing lives lived with disability.

In 2019, National Council on Disability (NCD), an independent federal agency, released series of reports on bioethics and disability.<sup>18</sup> One of these reports *Quality-Adjusted Life Years and the Devaluation of Life with a Disability* found “sufficient evidence of QALYs being discriminatory (or potentially discriminatory to warrant concern.”<sup>19</sup> NCD recommended an explicit ban on the use of QALYs in Medicare and Medicaid.<sup>20</sup> They also recommended that Medicaid “should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illness.”<sup>21</sup> NCD also recommended the use of alternative value assessment mechanisms and provided examples for the federal government and states to use.

The use of QALYs may also violate federal law. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by the federal government.<sup>22</sup> Title II of the Americans with Disabilities Act (ADA) extends this protection to programs and services offered by state and local governments.<sup>23</sup>

During the COVID-19 pandemic, OHP responded to the concerns of disability rights advocates about the allocation of scarce resources by developing a negotiated document on how to allocate scarce inpatient critical care resources in the pandemic. The Prioritized List should be given the same treatment. We urge OHP to abandon the use of the QALY and work with Disability Rights Oregon, Epilepsy Foundation Oregon, and other disability rights organizations to develop a better way to allocate scarce Medicaid dollars and care for people with disabilities in an equitable way.

### ***Oppose Restricting EPSDT Benefit***

We are opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). There are 5,400 children in Oregon with epilepsy and the purpose of the EPSDT benefit is to ensure that children receive appropriate health care. Limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services. We appreciate that Oregon is not proposing to limit access to medications for children. However, children with epilepsy do not need just their anti-seizure medications alone. They frequently, nearly always in Dravet syndrome, have related developmental disabilities or mental health needs, yet the current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including selective mutism, conduct and impulse disorders, deformities of the upper body and limbs, sleep disorders, and pica. Lack of sleep is a known seizure trigger,<sup>24</sup> and children with epilepsy are known to already have more sleep problems,<sup>25</sup> so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications,

<sup>16</sup> Oregon HERC. Multisector Intervention Report: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer. October 1, 2020. [https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening\\_finalized\\_10-1-2020PDF.pdf](https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening_finalized_10-1-2020PDF.pdf)

<sup>17</sup> Oregon HERC. Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring. October 4, 2018. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CardioMEMS-final.pdf>

<sup>18</sup> National Council Disability. Bioethics and Disability Report Series. Available at: <https://ncd.gov/publications/2019/bioethics-report-series>

<sup>19</sup> National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 6, 2019. [https://ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf), pg. 13.

<sup>20</sup> Ibid., pg. 14.

<sup>21</sup> Ibid., pg. 15.

<sup>22</sup> 29 USC Sec 794, 2017.

<sup>23</sup> 42 USC Sec 12131, 2017.

<sup>24</sup> Lanigar, S., & Bandyopadhyay, S. (2017). Sleep and Epilepsy: A Complex Interplay. Missouri medicine, 114(6), 453–457. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6139974/>

See also: <https://www.epilepsy.com/learn/triggers-seizures> and <https://www.epilepsy.com/learn/triggers-seizures/lack-sleep-and-epilepsy>

<sup>25</sup> <https://www.epilepsy.com/learn/challenges-epilepsy/sleep-and-epilepsy>



emergency room visits, hospital stays, and lost school days. The prioritized list also currently excludes treatment for conditions that can be a risk or side effect of epilepsy treatment, including paralysis of vocal cords or larynx, which can result from implantation of a Vagus Nerve Stimulation (VNS) device which is commonly utilized in patients with Dravet syndrome. Limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. Children of color are enrolled in Medicaid at disproportionately higher rates<sup>26</sup> and are also more likely to be affected by gaps in coverage.<sup>27</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit.

We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

We appreciate the opportunity to comment on this proposal and sincerely hope that our concerns are heeded so that people with Dravet syndrome and other forms of epilepsy can continue to access the care and medications that they need. If you have any questions, please contact us at [veronica@dravetfoundation.org](mailto:veronica@dravetfoundation.org).

Sincerely,

Veronica Hood, PhD  
Scientific Director  
Dravet Syndrome Foundation

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<sup>26</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. <https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf>

<sup>27</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://ccf.georgetown.edu/wp-content/uploads/2021/11/Gaps-in-Coverage-A-Look-at-Child-Health-Insurance-Trends-Center-For-Children-and-Families-georgetown.edu)