The voice of people living with chronic health conditions.

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March 25, 2013

Members of the Pharmacy and Therapeutics Committee (P&T)
Health Evidence Review Commission (HERC)
Oregon Health Authority
General Services Building
1225 Ferry Street SE, First floor
Salem, OR 97301

Members of the Oregon P&T and HERC Staff:

Thank you for the opportunity to provide testimony to you today. I am writing to express concern about the adoption of guidelines dealing with therapies "with marginal benefit and hight cost".

NWPEN supports the use of evidence informed outcome decisions as outlined in the Affordable Care Act (ACA), however I am concerned about the use of arbitrary guidelines with regard to the treatment of cancer patients who may be near the end of their lives.

Decisions around treatment are personal and unique, and we believe best left to the patient and their care providers. Regardless if a patient desires continued treatment to sustain life, palliative measures or hospice care, the choice cannot be dependent on solely on the cost of treatment versus the expected length of time that the treatment may offer.

It is my belief that implementing such practices places additional unnecessary barriers to care for already ill patients, and their caregivers who are navigating the health care system.

The need to control health care spending is very real and impacts all of us, however this example is simply one topic which is appealing because the cost of treatment is so great. I remind you that the only way see true savings in health care spending and improved community health is to prevent disease and chronic conditions before they occur.

The need to create cost savings is critical, however I fear this plan reminds me of the "death panels" fictitiously cited as the arbiters of life and death by opponents of ACA.

End of life decisions that are complicated by advanced diseases like cancer are difficult enough to manage without imposing more obstacles to overcome. I ask you to continue collecting data on these patients, their care and outcomes over the full implementation of the ACA (through 2017) before adopting finite measures which limit patient choices and options in their most difficult hours.

Respectfully,

BJ Cavnor
Executive Director

Written Testimony of the **Caring Ambassadors Program**
Lorren Sandt, Executive Director
P.O. Box 1748
Oregon City, OR 97045

Oregon Drug Use Review/Pharmacy & Therapeutics Committee
March 28, 2013

The Caring Ambassadors Program (CAP) is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written testimony regarding "Therapies with Marginal Benefit and High Cost Policy". The proposed HERC/P & T committee prioritization collaboration would violate federal law; the anti-discrimination provision of Patient Protection and Affordable Care Act (PPACA) and the federal Medicaid rebate statute.[1,2]

Our current healthcare system is not built around prevention. An individual should not be penalized if they are diagnosed at a later stage of disease when, in general, treatments are more costly and less effective. It is the system we have of acute care. Until we have a system of prevention in place, deciding treatment based on cost, or life expectancy, is discrimination. Diseases do not discriminate therefore it is vital that the HERC/P & T committee does not discriminate against any disease state, condition, or expected length of life.

The rules allow members of the P&T committee to make decisions based on "marginal benefit." Based on statistics? Statistics are the average. For an individual it is either 100% or 0%. How can this committee make that decision? You shouldn't value your effect on someone else's life in a monetary way. Consumers should be educated by their healthcare provider whose real life experience in treating patients and then be allowed to choose the best course of action for their condition, family values and culture.

Good policy is rational and consistent. Application of the HERC standard will inevitably be unpredictable and inconsistent. The HERC standards actually allow committee members to make decisions based on unknown information – the very definition of arbitrary. In the very example provided by the Oregon Health Authority, they note that "it is unknown" whether the drug mentioned would have a sufficiently positive impact on quality of life. The standard asks the P&T committee members to make broad decision on many patients based on literally no information.

CAP urges you not to discriminate based on disease or stage of disease. Thank you for your time and consideration. CAP greatly appreciates the work you and state agencies are doing to reach the goals of the Oregon Health Authority; improved lifelong health, increased accessibility to quality care and affordable care.

Sincerely,

Executive Director

1. Patient Protection and Affordable Care Act, Public Law No. 111-148, section 1302 (2010).
2. Section 1927 of the Social Security Act

MEMORANDUM

TO: **Oregon Drug Use Review/Pharmacy & Therapeutics Committee**

FROM: **James N. Gardner, Esq.**
Oregon Legislative Counsel for PhRMA

DATE: **March 28, 2013**

RE: **Federal Limits on Oregon's Ability to Limit Access of Medicaid Clients to Prescription Drugs**

I Overview

Two federal statutory provisions—section 1302 of the Patient Protection and Affordable Care Act (the anti-discrimination provision of PPACA) and section 1927 of the Social Security Act (the must-cover provision of the federal Medicaid rebate statute)—significantly limit the ability of the state of Oregon to restrict the availability of prescription drugs to Medicaid clients. For the reason stated herein, the proposed HERC/P & T committee prioritization collaboration would violate these key provisions of federal law.

II Background

The Oregon Drug Use Review/Pharmacy & Therapeutics Committee ("P & T committee") is in the process of developing a "Therapies with Marginal Benefit and High Cost Policy" that has been summarized by the P & T committee as follows:

> GOAL:
> Adopt a policy to assist the Pharmacy and Therapeutics Committee in identifying drugs that meet the criteria for a recommendation to the HERC Committee for further evaluation for the Prioritized List.
>
> 1. After a thorough clinical review of the evidence for a particular therapy in addition to cost discussion in executive session, the P & T Committee can recommend the drug be considered as part of this policy and recommendation to the HERC Committee.
>
> 2. Therapies that exhibit one or more of the following can be considered by the Committee:
> A. Marginal or clinically unimportant benefit, or
> B. Very high cost in which the cost does not justify the benefit, or
> C. Significantly greater cost compared to alternative therapies when both have similar efficacy.

A document issued by the Health Evidence Review Commission ("HERC") entitled "Therapies With Marginal Benefit and/or High Cost Issue Summary" (copy attached) sheds

further light on the policy under development by the P & T committee. A key statement in that document provides as follows:

> Question: Shall a guideline be adopted dealing with therapies with marginal benefit and high cost?
>
> Question Source: HERC Staff, P&T Committee
>
> Issue Summary: A number of recent issues have come up in which there are decisions around therapies that have marginal benefit and very high cost. HERC staff has been working with the Pharmacy and Therapeutics (P&T) Committee on how the Prioritized List interfaces with the work of the P&T committee.
>
> Historically, when there is a condition with treatments that have significantly different cost-effectiveness or marginal benefit, HERC has chosen to prioritized [*sic*] treatments both above and below the funded region of the List or not put the treatment of questionable benefit on the List at all. P&T is performing assessments on benefit as well as cost for a number of medications and interventions. HERC could potentially refer to assessments completed by the P&T as it relates to the Prioritized List. In this way, the principles for prioritization can take into account evidence and cost-effectiveness research that the P&T committee performs.

The attached HERC document goes on to cite as an example of this prioritization process a Prioritized List guideline for cancer treatment at the end of life that proscribes treatment with intent to prolong survival of a Medicaid client under the following circumstances:

> Treatment with intent to prolong survival is not a covered service for patients with any of the following:
>
> - Median survival of less than 6 months with or without treatment, as supported by the best available published evidence
> - Median survival with treatment of 6-12 months when the treatment is expected to improve median survival by less than 50%, as supported by the best available published evidence
> - Median survival with treatment of more than 12 months when the treatment is expected to improve median survival by less than 30%, as supported by the best available published evidence
> - Poor prognosis with treatment, due to limited physical reserve or the ability to withstand treatment regimen, as indicated by low performance status.

The attached HERC document concludes with a recommendation that HERC discuss adoption of a new ancillary guideline note for the Prioritized List to be entitled "ANCILLARY GUIDELINE XXX, THERAPIESWITH MARGINAL BENEFIT AND/OR HIGH COST." The substance of the proposed guideline would be as follows:

It is the intent of the Commission that therapies that exhibit one or more of the following characteristics generally not be included in the funded region of the Prioritized List:

i. Marginal or clinically unimportant benefits,
ii. Very high cost in which the cost does not justify the benefit, and/or
iii. Significantly greater cost compared to alternative therapies when both have similar efficacy.

Where possible, the Commission prioritizes pairings of conditions and treatment codes to reflect this lower priority, or simply does not pair a procedure code with one or more conditions if it exhibits one of these characteristics.

As codes for prescription drugs and certain other ancillary services are not included on the Prioritized List, it is more difficult to indicate the importance of these services through the prioritization process. The Commission recognizes the evidence-based reviews being conducted by the Pharmacy and Therapeutics Committee and hereby prioritizes those services found in Table XX located at www…(e.g., as of October 1, 2013) to be prioritized on the list listed below that corresponds with the condition being treated.

It is my understanding that the HERC has adopted this recommendation.

III The Adverse Impact on Oregon Medicaid Clients of the Proposed HERC/P & T Committee Prioritization Collaboration

The impact of the proposed HERC/P & T Committee collaboration on Oregon Medicaid clients would be straightforward and adverse. Patients suffering from ailments for which drug therapies are deemed to have marginal benefit and/or to impose very high costs for which the ensuing benefit is determined by HERC to be "unjustified" would be denied prescription drug coverage.[1] As discussed below, this proposed policy would run afoul of two key provisions of federal law.

IV Denial of Prescription Drugs to Oregon Medicaid Clients as a Result of the Proposed HERC/P & T Committee Prioritization Collaboration Would Violate Federal Law

Two federal statutory provisions—section 1302 of the Patient Protection and Affordable Care Act (the anti-discrimination provision of PPACA) and section 1927 of the Social Security Act (the must-cover provision of the federal Medicaid rebate statute)—would be violated if

[1] The currently codified authority contained in ORS 414.325(5)(c) for the Oregon Health Authority to withhold payment for drugs that are not funded on the Oregon Prioritized List of Health Services is not consistent with the federal Medicaid rebate statute discussed in this memorandum. The federal law requires a state Medicaid program to cover all of a manufacturer's covered outpatient drugs. This section cannot be waived by CMS. PhRMA has proposed an amendment to HB 2090 that would delete this unlawful provision.

Oregon Medicaid clients were denied coverage of prescription drugs as a result of the proposed HERC/P & T Committee prioritization collaboration.

A. Section 1302 of PPACA

Section 1302 of PPACA[2] provides that essential health benefits cannot be denied "to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life." Yet that is precisely what the HERC/P & T committee prioritization collaboration would accomplish, as the cancer treatment guideline given as an example by HERC unambiguously reveals. It is difficult to conceive of a clearer violation of section 1302.

B. Section 1927 of the Social Security Act

Section 1927 of the Social Security Act, 42 USC 1396r-8, requires a state Medicaid program to cover all of a manufacturer's covered outpatient drugs.

To be more specific, if a state chooses to provide a drug benefit under Medicaid, in order for federal matching funds to be available, the benefit must comply with the provisions of federal law. Since 1990, states have been required to comply with section 1927 of the Social Security Act.

Among other things, section 1927 provides that, if a drug's manufacturer enters into the federal Medicaid rebate agreement with the Secretary of HHS on behalf of the states, the drug must be covered by Medicaid when prescribed for a medically accepted indication (as defined in federal law). The drug may not be excluded by means of a formulary procedure unless that procedure meets specific criteria and uses specific types of information specified in federal law. Any prior authorization program used by a State must provide an answer within 24 hours of a request, and must dispense a 72 hour supply in case of emergency (including state inability to provide a timely answer). Any drug subject to utilization controls—even one that has been excluded pursuant to a formulary lawfully created under federal law—must be covered pursuant to a prior authorization program that meets the requirements above.

The only exceptions are a specific list of drugs that the federal law says a state may choose to exclude. The only drugs on the list are drugs used for weight loss or weight gain, fertility drugs, drugs for erectile dysfunction, drugs used for hair loss, drugs for symptomatic relief of cough or cold, prescription vitamins except for prenatal vitamins, nonprescription drugs, and drugs whose manufacturer conditions sale on the purchase of tests or a monitoring service.

All states must comply with section 1927 as a condition of receiving federal matching funds. The federal Secretary of HHS does not have authority to waive the applicability of section 1927 to any state.

In the case of the proposed HERC/P & T committee prioritization collaboration, denial of Medicaid coverage of federally qualifying prescription drugs on the basis of their purported marginal benefit or high cost would clearly violate section 1927.

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[2] Patient Protection and Affordable Care Act, Public Law No. 111-148, section 1302 (2010).

V Conclusion

For the reasons stated in this memorandum, the Oregon Pharmacy and Therapeutics Committee should decline to participate in the proposed HERC/P & T Committee prioritization collaboration.

National
Multiple Sclerosis
Society
Oregon Chapter

Oregon Pharmacy and Therapeutics Committee
Drug Use Research and Management Program
OHA Division of Medical Assistance Programs
500 Summer Street NE, E35
Salem, OR 97301-1079

March 28, 2013

Dear Members of the Pharmacy and Therapeutics Committee:

Thank you for the opportunity to provide comments today on the benefits of Ampyra for people living with multiple sclerosis. On behalf of the 7,600 people living with multiple sclerosis in Oregon, I offer the following testimony for your consideration.

Multiple Sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system. MS interrupts the flow of information within the brain, and between the brain and body. MS can cause blurred vision, loss of balance, poor coordination, slurred speech, tremors, numbness, extreme fatigue, cognitive deficits, and even paralysis and blindness. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. Because symptoms vary so much in people living with MS, as well as response to treatments, the National MS Society believes that all treatments available to treat the disease and its' diverse symptoms should be available to all those who live with this disease. Treatment decisions are best determined jointly by the treating physician and the patient.

Difficulty with walking, balance issues and coordination problems are among the most common symptoms of MS. In fact, in a 2008 online survey conducted on behalf of Acorda Therapeutics, Inc. and the National MS Society, 41% of people living with MS in the survey reported having difficulty walking. 70% of those with difficulty walking cited it was the most challenging aspect of having MS. Only 34% of people with MS with difficulty walking were employed.[i] Ampyra, which received FDA approval in January 2010 "to improve walking ability in patients with MS", is the only FDA approved agent with this indication. Ampyra works only for a relatively small percent of people living with MS, but it can be life changing for those who see the benefits.

In examining the benefits of Ampyra, I urge you to consider broader impact than simply the increase in walking speed. First, consider what one gains from an increase in walking speed. Bladder and bowel dysfunction are other common symptoms experienced by those living with MS. An increase in walking speed can greatly help someone manage these sometimes isolating symptoms.

Among those taking Ampyra who improved in walking speed, there was also a statistically significant improvement in leg strength.[ii] This improvement in leg strength could mean an exercise program is now a viable option for the individual.

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Based on data from the online survey previously mentioned, people with MS who have difficulty walking generally report not only negative impact on their mobility, but also restricted activities, a negative impact on emotional health and a higher need for assistance in performing daily tasks. Please consider this statement from the article cited about the online study: "The findings reported here showed that difficulty walking has a broad and substantial impact on daily activities, social function, employment and socioeconomic status." The benefits an individual living with MS may find from Ampyra are not just in walking speed, but in all of these things- improved social function, positive impact on daily activities and improved opportunities for employment and socioeconomic status.

I would like to share with you the story of EJ Levy, diagnosed with MS in her early thirties. EJ was an active hiker and skier with a fast-paced internet job. Within two years EJ had left her job and could walk very short distances with a cane, using a wheelchair for longer distances. Today, thanks to Ampyra, EJ is able to walk without a cane and hikes up to five miles. She says, "It's about quality of life. Having my mobility and my life back is priceless."

Diagnosed with MS in February 2012, Chet Arnett said Ampyra has made a difference. "My balance is better with Ampyra, as is my walking." He's seen overall improvements in steadiness, walking, and coordination, and that offers hope to continue living independently. He explained "A year ago I was worried about falling and needed assistance from others. I have much more confidence now and feel secure in my movement." Chet goes to the store, gets his mail, exercises and completes other daily activities without worry. "If I couldn't take Ampyra, my MS symptoms would be more pronounced, I wouldn't be able to walk as well as I do, and I'd need more help."

In your consideration of Ampyra, please think about EJ and Chet and the broad benefits people with MS have due to increased mobility. These benefits are more than marginal. For the percent of people for whom Ampyra works, the changes they see are substantial.

Thank you for your time and consideration. Please let me know if there is any additional information the National MS Society may provide.

Sincerely,

Carol Choutka

Carol Choutka
Program Manager
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[i]LaRocca, Nicholas G.; *Impact of Walking Impairment in Multiple Sclerosis*. Patient 2011: 4(3): 189-201.
[ii]Goodman AD, Brown TR, Cohen JA, Krupp LB, Schapiro R, Schwid SR, Cohen R, Marinucci LN, Blight AR; Fampridine MS-F202 Study Group. *Dose comparison trial of sustained-release fampridine in multiple sclerosis*, Neurology. 2008 Oct 7;71(15):1134-41. Epub 2008 Jul 30.

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LaRocca NG. Impact of Walking Impairment in multiple Sclerosis. The Patient: Patient-Centered Outcomes Research. 2011;4(3):189–201.