Advocacy for Patients with Chronic Illness, Inc.

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VIA ELECTRONIC MAIL

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VIA FIRST CLASS MAIL

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Dear Medical Inefficiency Committee Members:

I am unable to participate in person at your scheduled hearing on February 8, 2010 because our caseload has become so extraordinary that I cannot leave the office. Due to the budget cuts both in Connecticut and elsewhere, it no longer is unusual for me to get phone calls from people living in cars, seniors who have lost homes to foreclosure who no longer can get their medications through the State (because the Medicare Part D wraparound has been eliminated), and transplant recipients who cannot afford their anti-rejection medications and, thus, are dying.

It is because of these people, though, that I believe the work you are doing is so critically important. If you get it wrong, people will suffer even more. Thus, I am writing to provide you with the insight I have gained from the work I do every day.

One area in which the Department of Social Services seeks to change the definition of Medical Necessity/Medical Appropriateness is by replacing the current restriction on substituting a prescribed treatment with a cheaper alternative unless the substitute treatment is "equally effective." The Department would instead adopt the much looser restriction that the less expensive substituted treatment approved by it or its HMO contractor must be "similarly effective." This change would substantially diminish the quality of care for vulnerable low-income Medicaid recipients and provide them with even

less protection than is available to commercial managed care enrollees, who are protected by a state statute barring substitution unless the cheaper alternative is "as likely to produce equivalent therapeutic or diagnostic results...." C.G.S. § 38a-513c.

Unfortunately, even under this "therapeutic equivalence" standard, commercial insurers routinely deny access to needed treatments and require a patient to use or try a cheaper but less effective, or harmful, treatment instead Advocacy for Patients does more commercial insurance work than Medicaid or Medicare. Most commercial insurers have adopted a policy called "step therapy." Step therapy means that, if you need an expensive medication, you can't have it if there is a less expensive medication that the insurer believes is sufficiently similar in effect. Step therapy kills.

I can provide many examples. In what I consider to be the most egregious, some insurers are requiring patients with Crohn's disease to try a drug called Tysabri rather than giving them what their doctor prescribes, i.e., a higher dosage of a safer drug called Humira, or a newer drug like Cimzia. Tysabri initially was so terrifying that it was pulled from the market. Now that it is re-released, it carries with it a black box warning of death from progressive multifocal leukoencephalopathy. Patients who take Tysabri must participate in a registry, have monthly blood tests that are sent to the drug manufacturer, and report to the drug manufacturer every six months. Humira and Cimzia are other drugs used to treat Crohn's disease, but they carry no such dire warnings. Yet there are insurance companies trying to force patients to try Tysabri because they are able to negotiate a better price with the manufacturer of Tysabri than they can negotiate with the manufacturers of Humira or Cimzia. Deaths from Tysabri are well-documented. Still, when medical similarity is the watchword, apparently those deaths are acceptable.

Similarly, multiple sclerosis and lupus patients have a difficult time obtaining coverage for intravenous immune globulin unless they have tried and failed a list of other medications that have serious side-effects, including intravenous corticosteroids and several biologics (including the aforementioned Tysabri). I have one young client with Hashimoto's encephalopathy whose insurer is authorizing intravenous immune globulin at four month intervals, preferring intravenous Solu-medrol, a steroid. When on the IVIg, he can speak and learn and walk; but every four months, his insurer forces him to come off the IVIg to see if it is fair to infer that the IVIg is the cause of the improvement. When he is off the IVIg, he regresses to a wheelchair and all cognitive function is lost because the Solu-medrol simply doesn't work. The cycle repeats every four months, and is required if the insurer is going to cover the IVIg at all.

There are many more benign examples. Patients with upper-gastrointestinal disorders like gastroespohageal reflux disease (GERD) or gastroparesis who need a proton pump inhibitor that is not on their insurer's formulary – Aciphex, Protonix – are being required EVERY YEAR to try Prilosec, Prevacid, and Nexium BEFORE their insurer will approve a one-year supply of the more expensive medication. For a patient with gastroparesis (like me), for example, that means vomiting whatever is eaten for a period of months just to prove to the insurance company that the less expensive medications are not truly medical equivalents.

This is what happens when insurers get into the business of prescribing by deciding what drugs are "similar" enough. In the early days of managed care, courts bought insurers' arguments that they were not prescribing; they were only stating what they would and would not cover. However, this new trend has insurers, without regard for their own liability, firmly in the business of prescribing – and in some cases, the drugs they prescribe

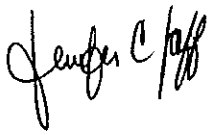
have life-threatening side-effects that are being overlooked in the interest of cost. Whether or not to take Tysabri and risk one's life should be a decision that an informed patient and his or her treating physician make, not one that is made by a doctor sitting at a desk who may never have treated a patient with Crohn's disease or multiple sclerosis or lupus, and may never have actually practiced medicine at all.

Given the harm that insurers already impose on commercial managed care enrollees even under the relatively protective "equivalent therapeutic or diagnostic results" language, it is readily apparent that the Department of Social Services' proposal to replace "equally effective" with the far weaker "similarly effective" or "comparably effective" language, under the current Medicaid medical necessity/medical appropriateness definition, would be harmful to thousands of Medicaid enrollees; there simply is no avoiding this. If patients are forced to take medication that is approved because DSS could get a good deal on it and because the Department deems the substitute drug to be "similarly effective," rather than being allowed to take medication that will better address the medical problem without risky, debilitating side-effects, somebody will die. I truly believe that the consequences are that severe. Can you tolerate a system that forces patients to risk their lives for a cheaper medication when a slightly more expensive but entirely safe medication is available? Is it okay for my insurer to force me to undergo at least one month every year of uncontrolled vomiting while I try a less expensive medication that I have tried every single year, with the exact same result?

I urge you to rein in the Department of Social Services before they really harm somebody, and reject the proposal to allow it or its contracting HMOs to substitute a prescribed treatment with one which is "similarly effective." Indeed, the State's liability in that instance will cost far more than simply providing the medically necessary treatment in the first instance.

Thank you.

Sincerely,



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* Admitted to practice law in Connecticut, New York and the District of Columbia. Advocacy for Patients is a 501(c)(3) tax-exempt organization and does not charge patients for its services. Advocacy for Patients is funded by, among other sources, grants from foundations and companies that engage in health care-related advocacy, manufacturing, delivery and financing. A list of grantors will be furnished upon request.