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Roderick Bremby
Commissioner
Department of Social Services
55 Farmington Avenue
Hartford, CT 06106

Re: Access to Medications to Treat and Cure Hepatitis C Virus

Dear Commissioner Bremby:

The undersigned organizations, which represent clients at risk for and living with the hepatitis C virus (HCV), are gravely concerned about the new clinical criteria for HCV treatment under Connecticut's Medicaid program, as announced in the department's bulletin to providers issued on November 24th, entitled "New Hepatitis C Prior Authorization Criteria - Sovaldi™", which went into effect on December 10, 2014, as amended via a new Sovaldi prior authorization request form circulated on or about January 22, 1015.

We would like to illustrate our specific concerns with the policy under federal and state Medicaid law. We are optimistic that we can find agreement around this issue and our hope is the policy can be revised to achieve our mutual priorities.

As we're sure you know, under federal Medicaid law, notwithstanding cost, if a drug is FDA-approved, subject to a rebate agreement with the manufacturer, and not in one of the few categories in which a state is allowed to exclude coverage (for adults only, none of which are applicable here), the drug must be made available wherever medically necessary, although prior authorization (PA) may be imposed[1]. Solvaldi, being FDA-approved, subject to such a rebate agreement, and not within one of those excluded categories, must be covered by every state that has an optional Medicaid pharmacy program, including Connecticut.

A state may, of course, limit payment for a drug to (1) FDA-approved uses plus (2) other medically accepted indications, i.e., off-label uses, specified in one of three compendia set forth in the federal Medicaid statute.[2] Sovaldi has been broadly approved by the FDA to treat patients with HCV genotypes 1 through 4, and it is, to our knowledge, not yet being prescribed for any other purposes.[3]

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[1] 42 U.S.C. § 1396r-8(d)(4)(D), *see* 42 C.F.R. § 440.230(d).

[2] 42 U.S.C. §1396r-8(d)(4)(C); *see* 42 U.S.C. § 1396r-8(d)(1)(B)(i).

[3] Beyond these pharmacy-specific statutory provisions, the long-standing set of general federal Medicaid regulations related to "amount, duration and scope," at 42 C.F.R. § 440.230(b) and (c), provide that "[e]ach [type of] service must be sufficient in amount, duration and scope to reasonably achieve its purpose" and that "[t]he Medicaid agency may not arbitrarily deny or reduce the amount, duration or scope of a required service under 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." There is extensive

Federal law requires that all Medicaid-covered services be furnished with "reasonable promptness."[4] Federal regulations under this provision require that a person be able to apply for Medicaid services without delay.[5] Federal law also requires that a hearing be offered to anyone denied specific services, with a written notice to the enrollee explaining the reason for the denial and providing information about the means to access a hearing.[6]

These strict federal requirements are reinforced by state Medicaid law. Under the Connecticut Medicaid statutory definition of medical necessity, Conn. Gen. Stat. § 17b-259b(a), a state must pay for any kind of covered treatment under Medicaid, at least where "[c]onsistent with generally-accepted standards of medical practice," provided the requested treatment is "not more costly than an alternative service or sequence of services ***at least as likely to produce equivalent therapeutic or diagnostic results***." (emphasis added). The statute also requires that medical necessity determinations be "based on an assessment of the individual and his or her medical condition." § 17b-259b(a)(5)

The new policy codified in PB 2014-83, issued on November 24, 2014, and the revised prior authorization request form issued about two weeks ago, violate state and federal Medicaid law by declaring that Sovaldi can not be provided under Medicaid if the specific clinical criteria in the bulletin are not met. There is no exception process whereby the treating provider can explain why individual medical need is established, under the long-standing state statutory definition of medical necessity, regardless of the result when applying the bulletin's clinical criteria. The statute requires that "[c]linical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and ***shall not be the basis for a final determination of medical necessity***." C.G.S. § 17b-259b(b)(emphasis added). Several of the restrictive criteria provided in the bulletin and prior authorization request form are quite harmful, as well as illegal. We will provide some select examples below.

The most straightforward example is the metavir 3 or 4 requirement. Medical need under the Medicaid medical necessity standard has never been limited to individuals with organ damage, even before the statutory codification. That definition mandates coverage of "health services required to ***prevent***, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning."[7] Critical to invalidating the cost-motivated policies in the bulletin, the statute provides that an

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case law under § 440.230, including drug cases, which make clear that categorical declarations of non-coverage or of non-coverage based on the **extent** of disease are not permissible. *See Weaver v. Reagan*, 886 F.2d 194 (8th Cir. 1989)(invalidating under § 440.230(b) state rule limiting AZT for individuals with AIDS to those with certain symptoms, including a CD4 count under 200). *See also Ledet v. Fischer*, 638 F.Supp. 1288 (M.D. La. 1986)(state refusal to pay for eyeglasses, an optional category of benefits, except for post-cataract surgery patients, invalidated under 42 C.F.R § 440.230(b)).

[4] 42 U.S.C. § 1396a(a)(8).

[5] 42 C.F.R. § 435.906.

[6] 42 U.S.C. § 1396a(a)(3); 42 C.F.R. § 431.200, et seq.

[7] C.G.S. §17b-259b(a)(emphasis added).

alternative treatment can be substituted **only** if it is "not more costly than an alternative service or sequence of services *at least as likely to produce* ***equivalent therapeutic or diagnostic results*** as to the diagnosis or treatment of the individual's illness, injury or disease."[8]

The metavir 3 or 4 requirement, which is a test for a high level of organ damage, does not meet any of these standards. It also does not meet the federal statutory and regulatory requirements which prohibit categorical limitations on treatment with an FDA-approved drug, especially when consistent with what is set forth in the FDA's labeling requirements. It does not meet the narrow circumstances set forth in the Medicaid Act where coverage can be excluded for an identified population with a particular disease, namely, where a covered drug, based on information from both the manufacturer and in the recognized compendia of off-label usages, "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary."[9] Completely apart from recognized off-label uses, the manufacturer of Sovaldi says nothing in its labeling about excluding from treatment the population with HCV who have metavir scores under 3, who have malignancies, who are pregnant (except if they are also taking ribavirin or peginterferon alfa/ribavirin), etc. The restriction also violates the general Medicaid scope of service regulations.[10]

The second example is the prohibition on treatment if the patient previously had either a full or incomplete course of Sovaldi. This exclusion violates the state medical necessity statutory definition because it attempts to exclude all patients who have already started and not completed a regimen with Sovaldi, or completed this therapy but did not get a cure, which is called a "sustained virologic response" (SVR). There are now reports in the literature of patients who took Sovaldi and Olysio together who eventually showed continued HCV infection, and some of them are now being re-treated. In addition, a few patients fail to complete a course of treatment, due to losing Medicaid coverage, severe illness or other issues not the fault of the patient -- perhaps the individual has already had his or her access to further treatment blocked due to the Sovaldi policy change in December. Whether individuals should be re-treated in these cases is a medical and ethical question, and one which must be assessed on a case by case basis applying the medical necessity definition to each patient, **if** a treating provider, weighing all of the factors, chooses to request prior authorization.

The criteria barring patients who are taking other products believed to reduce the effectiveness of Sovaldi, while perhaps appearing reasonable on their face, also violate state and federal law. While there are known drug interactions with sofosbuvir-based regimens which should be avoided, there are gray areas in which there is some interaction but the drug is not contraindicated -- this holds true for a number of other antiretroviral regimens. For example, the FDA labeling for Sovaldi says only that "Coadministration is not recommended" with anticonvulsants, *compare* label regarding St. John's wort ("Sovaldi should not be used with St.

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[8] C.G.S. § 17b-259b(a)(4)(emphasis added).
[9] 42 U.S.C. § 1396r-8(d)(4)(C).
[10] 42 C.F.R. § 440.230(b) and (c), *see Weaver v. Reagan*, 886 F.2d 194 (8th Cir. 1989)(invalidating state rule limiting AZT for individuals with AIDS to those with certain symptoms, including a CD4 count under 200).

John's wort"). It will be for the treating provider to decide whether to follow this advice and, if so, which drug(s) to drop, subject to DSS's review of a request for prior authorization for the particular patient.

Similarly, while the FDA label recommends taking Sovaldi with ribavirin or peginterferon alfa/ribavirin, it is only the latter drugs, **not** Sovaldi, which are contraindicated for pregnancy. In addition, since that label was produced, interferon is no longer the standard of care even for Genotype 1 of Hepatitis C. And, in the case of ribavirin, since November, 2014, there is now an FDA-approved combination which can be used instead, Sovaldi plus Olysio, avoiding entirely the use of interferon or ribavirin. The provider may, in the case of a patient who is pregnant or may become pregnant but has an urgent need for Hepatitis C treatment, prescribe the primary medication, Sovaldi, **without** the adjuncts which are contraindicated for pregnancy. But in the absence of an opportunity for an individualized review of the patient, his or her various medical conditions, the need for treatment of each of them and possible changes in prescriptions to accommodate any contraindication, as mandated under state law, it is impermissible to apply these categorical exclusions on coverage and declare across the board that approval will **never** even be considered in these situations.

In addition to the above examples, the requirement that the "patient must undergo treatment with SovaldiTM for an FDA approved indication and [it must be] prescribed with FDA approved combination therapy," is inconsistent with federal Medicaid law. Federal law mandates that other medically accepted indications, *i.e.*, off-label uses specified in one of the three compendia specified in the federal Medicaid statute, must also be covered.[11] The development of indications beyond the FDA-approved therapies has already occurred in the case of Sovaldi: while the label recommends interferon as an adjunct for Genotypes 1 and 4, this is no longer the standard of care at least for Genotype 1; Sovaldi with ribavirin alone (or a substitute for ribavirin) is recommended. *See* American Association for the Study of Liver Diseases/Infectious Diseases Society of America Guidelines, at www.hcvguidelines.org (updated January 25, 2015). And there will very likely be new usages as providers innovate. For example, although the FDA labeling says "[a]vailable data on subjects with genotype 5 or 6 infection are insufficient for dosing recommendations;" this could soon become a recognized off-label use. A policy that categorically limits coverage to only FDA-approved uses is stagnant and dangerous, and runs afoul of the federal Medicaid requirements; it should be removed.

Apart from the above examples, the policy allowing only a handful of kinds of specialists to provide a written consult as a prerequisite for approval of Sovaldi conflicts with the "reasonable promptness" requirement in the federal Medicaid statute, 42 U.S.C. § 1396a(a)(8). Medicaid patients have extreme difficulty in obtaining access to specialists in Connecticut, for a variety of reasons, including reimbursement rates and specialist preferences. Most of the federally qualified health centers do not have an ID specialist on staff. By contrast, there are many experienced prescribers who have long been treating HCV patients and are fully qualified to make the assessment about the appropriateness of prescribing this drug, or any other HCV drugs, often with much more experience treating HCV than the designated kinds of specialists. This includes but is not limited to HIV specialists, whom we understand you are now considering to be qualified specialists. Limiting the prescribing of Sovaldi to providers who are, or who have

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[11] 42 U.S.C. §1396r-8(d)(4)(C); 42 U.S.C. § 1396r-8(d)(1)(B)(i).

obtained written consults from, board-certified gastroenterologists, hepatologists, liver transplant specialists, or infectious disease or HIV specialists will greatly reduce access to treatment. The long delays before such appointments can occur will mean long delays before essential treatment begins, in some cases causing irreparable harm, in violation of federal Medicaid law.

Lastly, under federal Medicaid law, an enrollee is entitled to request any services under Medicaid and to appeal any denial of services, and "[t]he agency may not limit or interfere with the applicant's or beneficiary's freedom to make a request for a hearing."[12] The right to a hearing, as also provided in both the Due Process Clause of the Fourteenth Amendment and the federal Medicaid Act, at 42 U.S.C. § 1396a(a)(3), necessarily includes the right to a written notice informing a Medicaid enrollee of the denial and of the means to appeal it. Sovaldi must be submitted through a treating provider, but the providers also are instructed in the bulletin and both the original and revised prior authorization request forms that they **must** use the specific PA request form included with the bulletin, and that form expressly declares that the provider must "certify that use of SovaldiTM for this patient is consistent with the above criteria/guidelines," i.e., they are not allowed to **request** PA on behalf of a patient who does not meet those narrow criteria, which are not consistent with the FDA labeling or state law and are rapidly becoming seriously outdated. Accordingly, the filing of a request for PA is completely blocked whenever a provider with a patient who does not meet these narrow and illegal criteria seeks treatment with Sovaldi for that patient, with the result that no denial notice is issued and no hearing is offered in these situations, in violation of the Medicaid regulations and the Due Process Clause.

We respectfully request that your agency immediately remove the restrictive clinical criteria provisions as absolute requirements, remove the certification requirement, and indicate in a revised bulletin that all requests for prior authorization for Sovaldi will be individually assessed for medical need pursuant to C.G.S. § 17b-259b. We would be more than happy to discuss this matter with you further or offer our assistance in these revisions.

We thank you in advance for your prompt response.

Respectfully yours,

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[12] 42 C.F. R. § 431.221.

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cc: Kate McEvoy, Medicaid Director
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