Health Consumer Alliance

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Sent via email to Neal.Kohatsu@dhcs.ca.gov and Julia.logan@dhcs.ca.gov

June 2, 2015

Neal Kohatsu MD, MPH, Medical Director
Julia S. Logan MD, MPH, Quality Officer
Office of the Medical Director
California Department of Health Care Services
1501 Capitol Ave., Suite 6001, MS: 0000
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Drs. Kohatsu and Logan,

We are writing on behalf of the Health Consumer Alliance (HCA), a statewide collaborative of consumer assistance programs operated by community-based legal services organizations, which includes: Bay Area Legal Aid, California Rural Legal Assistance, Central California Legal Services, Greater Bakersfield Legal Assistance, Legal Aid Society of Orange County, Legal Aid Society of San Diego, Legal Aid Society of San Mateo, Legal Services of Northern California, Neighborhood Legal Services of Los Angeles County, the Western Center on Law and Poverty, and the National Health Law Program. The HCA thanks you for the opportunity to comment on the draft version of the updated DHCS Hepatitis C treatment and utilization policy for Direct-Acting Antiviral Therapy in the Management of Hepatitis C. We commend DHCS for expanding the utilization policy to increase the number of people living with hepatitis C who are eligible for treatment through Medi-Cal. This draft makes several important changes to the previous policy, including recognizing that treatment is often clinically appropriate for people with less-advanced stages of liver disease, reducing the amount of documentation required before treatment may commence, and affirming that a person's history of substance use or mental illness is not an appropriate reason to deny care. We applaud DHCS for making these significant changes which will dramatically improve the lives and clinical outcomes for thousands of Medi-Cal beneficiaries who are living with hepatitis C.

While we appreciate the significant improvements DHCS has made to its policy, we believe that there are still areas where policy changes or clarifications are needed. We have provided line edits to your draft document, which are attached to this letter. We also submit the following over-arching comments for your consideration.

- **DHCS must not unduly limit persons who may be considered for treatment.**

The new treatments available for hepatitis C cure the disease in over 90% of cases—Harvoni cures 94% of cases. They are clinically appropriate to treat anyone with hepatitis C, regardless of fibrosis score; moreover, because hepatitis C is a chronic infectious disease, everyone living with the virus

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has a medical necessity to be treated and cured. Thus we urge DHCS to amend the policy to provide for treatment for all patients with hepatitis C who are likely to adhere to the treatment regimen and who are identified by their physicians as appropriate treatment candidates. Requiring most patients to wait until their liver disease is at an advanced stage before they may receive a curative treatment will force patients to live with a chronic, infectious, life-threatening disease and endure significant damage to their livers before they may be offered a cure. Because hepatitis C is a communicable disease, delaying a cure also puts other people at risk as those infected may spread the disease. Such policy is inconsistent with Medi-Cal's directive to ensure treatment is available whenever "it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." Welf. & Inst. Code § 14059.5. DHCS must amend its policy to permit treatment for anyone infected with hepatitis C, without respect to fibrosis score.

If DHCS does not eliminate the fibrosis score requirement in this policy, we urge DHCS to enlarge the categories of individuals who will be considered candidates for treatment at earlier stages of hepatitis C. First, we strongly encourage DHCS to include a category for health care workers as recommended by the AASLD guidelines. Second, we suggest that DHCS include a "catch-all" category that would permit individuals with early stage hepatitis C to be considered for treatment based on individual circumstances on a case-by-case basis. Finally, since liver biopsies are invasive and associated with potential severe side effects, DHCS should clarify that biopsies should be used as evidence of fibrosis only when other types of evidence are not available or appropriate for the patient.

- **DHCS must eliminate discriminatory and unsound limitations on treatment for people with substance use disorder or mental health conditions.**

We urge DHCS to eliminate sections C and D from this document. The criteria outlined in these sections are not relevant to medical necessity. They may have some limited relevance to patient readiness and adherence, and to that extent some of the considerations outlined in these sections may be incorporated into section B. We are concerned that by calling out substance use disorder and mental illness, the policy suggests that these conditions are appropriate grounds for denial of treatment. We do not believe that such denials are consistent with DHCS's intent, which we understand to be aimed at ensuring that individuals with a history of substance use or mental illness be evaluated on a case-by-case basis to determine their readiness and ability to adhere to treatment. Since all evaluations of readiness and ability to adhere should account for individual factors including patients' comorbidities and relevant medical history, there is no need to treat those with a history of substance use or mental illness differently than other patients. Rather, requiring addition scrutiny of patients with these conditions raises a specter of unlawful discrimination based on medical condition. *See* 42 C.F.R. § 440.240 (diagnosis-based discrimination in Medicaid prohibited); *see also* Health & Safety Code §§ 1367.8, 1373(f) (Knox-Keene anti-discrimination provisions); 42 U.S.C. § 18116(a) (ACA non-discrimination provision); 29 U.S.C. § 794 (prohibition on disability discrimination in federal programs). DHCS should eliminate sections C and D.

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If DHCS declines to delete sections C and D into section B as described above, we urge DHCS to rewrite these sections to clearly explain to providers and plans that treatment denials may not consider factors that are not related to readiness, ability to adhere, or medical necessity.

First, DHCS must not allow providers or plans to deny treatment based on a patient's past substance use. We appreciate that in the new policy, DHCS explicitly acknowledges that: "There are no published data supporting a minimum length of abstinence as an inclusion criterion for hepatitis C virus antiviral treatment, while multiple studies show successful treatment of patients who have short durations of abstinence or infrequent use of alcohol." Given the state of current medical evidence, DHCS must not merely "strongly discourage" providers and plans from denying care to individuals with a history of substance use or abuse, but must prohibit such denials. Denying care on a basis that has no clinical support is "arbitrary and unreasonable," and violates federal Medicaid law. *Allen v. Mansour*, 681 F. Supp. 1232, 1239 (E.D. Mich. 1986) (holding state's requirement that Medicaid beneficiaries abstain from alcohol and drugs for two years before they may be considered for a transplant is unlawful); *cf. Jeneski v. Myers*, 163 Cal. App. 3d 18, 33 (1984) (state may not "ignore[] the necessity that some patients have for drugs . . . . [as determined] on a patient-by-patient basis").

Second, DHCS must not allow providers or plans to deny treatment based on a patient's current substance use, but should direct providers and plans to coordinate care with substance use treatment providers when appropriate and practicable. Again, we are not aware of any clinical evidence to suggest that active substance use contraindicates treatment for hepatitis C. Rather, as DHCS acknowledges, "multiple studies show successful treatment of patients who have short durations of abstinence or infrequent use of alcohol." We appreciate that current substance use may interfere with a patient's ability to adhere to treatment, and is an appropriate consideration in that respect. But patients whose substance use warrants treatment should be offered such treatment and counselled on beginning treatment for hepatitis C and substance use disorder in tandem. We note that substance use disorder treatment is a Medi-Cal benefit that must be universally available when medically necessary. *See* APL 15-008; *see also Sobky v. Smoley*, 855 F.Supp. 1123 (1994). There may be pragmatic considerations that restrict a provider overseeing a patient's hepatitis C treatment from closely coordinating care with a provider overseeing treatment for substance use disorder, and we commend DHCS for not making such coordination a mandatory condition of treatment. But we urge DHCS to clarify in this policy that all patients whose substance use warrants a referral to treatment should be given that referral. DHCS must also clarify that patients who are currently using alcohol or other drugs may not be barred from treatment solely on the basis of their substance use, since such denials lack a clinical basis.

Finally, DHCS must not allow providers or plans to deny treatment solely based on a patient's current or past mental health condition. We appreciate that regimens that contain interferon may be contraindicated for individuals with certain mental health diagnoses, and suggest that DHCS ensure that prescribing providers screen for those conditions, along with other conditions that can be exacerbated by interferon use like blood clotting disorders, heart disease, diabetes, thyroid disorders, and anemia. There is no reason to single out mental health conditions to be treated differently from other physical health conditions for which certain treatments may not be clinically

appropriate, and doing so again raises the specter that DHCS is condoning unlawful discrimination by providers and plans. Moreover, since there is now a hepatitis C treatment that does not contain interferon—Harvoni—providers should be directed to consider prescribing that treatment for all patients who have comorbidities that contraindicate the use of a medication that contains interferon. Again, if DHCS does not remove this section per our suggestion above, it must at a minimum clarify that individuals with a current or past mental health condition may not be denied treatment solely on the basis of that condition.

- **DHCS should remove proposed restrictions on replacing lost or stolen medications.**

We are extremely concerned that the proposed limitations on replacing medications that are lost or stolen are overly restrictive and punitive. These limits are inconsistent with current DHCS policy, which permits "[e]arly refills . . . if the medications are lost or stolen," while requiring a pharmacist to confirm the early refill with the prescribing provider in certain instances. Cal. Dept. of Health Care Servs., Pharmacy Benefit Frequently Asked Questions at q.2, http://www.dhcs.ca.gov/services/Pages/PharmacyBenefitsFrequentlyAskedQuestions.aspx (last visited May 29, 2015); *see also id.* at q.9. DHCS's current policy is sensible and fair, and should continue to apply to hepatitis C treatments. Treatments for hepatitis C are not susceptible to overuse or abuse, and they have no street value; thus there is no justification for placing additional limitations on these medications. For one, there may be instances where a person does not know whether medications were lost or stolen (e.g., pills missing from a purse after a ride on public transit); it is nonsensical and burdensome (to the beneficiary and to taxpayer resources) to require a beneficiary to document a possible theft in these cases. For another, many Medi-Cal beneficiaries are homeless and do not always have a safe place to store medications, and many other beneficiaries have co-conditions or are taking other medications known to affect memory. While we anticipate that beneficiaries will make every effort to hold on to these curative medications, beneficiaries should not be punished for circumstances beyond their control. Finally, it makes no logical sense to stop a beneficiary's course of curative treatment because the person loses medications on one occasion; once DHCS has invested in a person's treatment, it should work to ensure adherence to the treatment rather than punish the person for an honest mistake or accident.

Moreover, under federal Medicaid law, DHCS is required to ensure that beneficiaries receive a 72-hour supply of medications during an emergency. 42 U.S.C. § 1396r-8(d)(5)(B).The proposed draconian limitations on replacing lost or stolen medications violate this provision, as they provide no exception to allow a 72-hour supply when the drugs are lost or stolen during an emergent situation. Finally, there is no rational basis for DHCS's decision to treat beneficiaries with hepatitis C differently than other beneficiaries when it comes to lost or stolen medications, and this different treatment suggests unlawful discrimination based on diagnosis. *See* 42 C.F.R. § 440.240 (diagnosis-based discrimination in Medicaid prohibited); *see also* Health & Safety Code §§ 1367.8, 1373(f) (Knox-Keene anti-discrimination provisions); 42 U.S.C. § 18116(a) (ACA non-discrimination provision); 29 U.S.C. § 794 (prohibition on disability discrimination in federal programs).

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- **DHCS should not restrict treatment when there is good cause for non-adherence and missed appointments.**

We urge DHCS to make clear that good cause for non-adherence is not an appropriate reason to deny future treatment. There may be some cases where a person begins a course of treatment, but unexpected circumstances force the person to terminate treatment, or otherwise interfere with the person's ability to comply with the prescribed regimen. For example, a person might get into a car accident during the course of treatment and miss several days of treatment. Similarly, someone may unexpectedly become pregnant during treatment and be forced to terminate the treatment regimen early. These kinds of non-adherence do not warrant a future bar to treatment. Whether past non-adherence is an indication that a person will not adhere again must be evaluated on a case-by-case basis in light of the individual's circumstances.

Similarly, DHCS should clarify that individuals who are otherwise eligible for treatment should not be barred from such treatment on the basis of past missed appointments unless the provider determines that the person lacked good cause for missing the appointment. Many Medi-Cal beneficiaries lack reliable transportation and child care, and last-minute emergencies or delays can cause them to miss medical appointments with no fault of their own. These problems are often exacerbated in rural parts of the state, where beneficiaries frequently have to travel long distances to see a provider. Where beneficiaries have made a good faith effort to keep or reschedule missed appointments, they should not be penalized with the denial of curative treatment because a babysitter didn't show up, or a bus was late.

- **DHCS should clarify that all qualified and contracted providers may prescribe.**

The current treatment policy requires that: "Medications are advised to be prescribed by or in consultation with a provider who has extensive experience treating Hepatitis C." The proposed update eliminates any mention of provider qualifications. We are concerned that the absence of guidance in this area will result in plans restricting the number of providers who may prescribe treatment as a cost-saving mechanism. We are already aware of at least one plan that has allowed only two providers in an entire county to prescribe the new hepatitis C treatments, which has resulted in significant access problems for its Medi-Cal enrollees. Minimally, DHCS should strengthen the current policy and require that a provider "experienced" with the treatment of hepatitis C may provide the service. The policy should affirmatively preclude plans from limiting the number or type of prescribing providers to the exclusion of otherwise qualified and experienced providers already in their network. Moreover, in an effort to include, in both number and type, all otherwise qualified and experienced providers, DHCS' policy should clarify that Medi-Cal Managed Care plans cannot impose excessive verification of provider credentials to further restrict access to hepatitis C treatments. For example, verification of the prescribing provider's Fellowship or Board Certification in Hepatology or Gastroenterology is not relevant to the individual patient's medical necessity and is not an appropriate basis to deny treatment. We urge DHCS to closely monitor its plans to ensure that the plans are not restricting access to treatment by limiting the number or type of qualified provider who may prescribe.

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The HCA appreciates DHCS's work to improve its treatment utilization policy for beneficiaries with hepatitis C. The proposed revision makes huge strides to improve access to care in Medi-Cal, and we applaud DHCS's efforts to maintain a treatment policy consistent with the current standard of care. We hope you will consider our suggestions to improve the revised policy further. . If you have any questions or need any further information, please contact Abbi Coursolle (coursolle@healthlaw.org; 310-736-1652), Staff Attorney, at the National Health Law Program. Thank you again for the opportunity to comment on this draft, and for your consideration of our comments.

Sincerely,

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National Health Law Program