CALIFORNIA DEPARTMENT OF CORRECTIONS

HEPATITIS C CLINICAL MANAGEMENT PROGRAM

March 2004

Hepatitis C Clinical Management Program

I. POLICY

The Health Care Services Division shall operate a Hepatitis C (HCV) Clinical Management Program that ensures delivery of appropriate clinical services by an interdisciplinary team for the diagnosis and management of chronic HCV. A system of data management and reporting will be maintained to assist in clinical, administrative, and quality management decisions.

II. PURPOSE

The California Department of Corrections HCV Clinical Management Program ensures a consistent, appropriate, effective, and efficient approach to the clinical management of persons infected with HCV.

III. PROCEDURE

A. Phase I: Screening and Initial Diagnosis (See Attachment I)

1. HCV Screening will be provided to all inmate-patients who request it, and offered to all inmate-patients who have a history of intravenous drug use or other risk factors for, or clinical findings compatible with, HCV. Each of these inmate-patients shall receive the Hepatitis C Patient Information Handout. See Attachment A. A copayment will not be incurred for the initial request to be tested for HCV.

2. All inmate-patients who request, or who are offered and agree to screening shall have a hepatitis panel and liver function tests obtained.

3. All inmate-patients found to have the antibody to HCV shall have the viral presence checked by the qualitative polymerase chain reaction (PCR) test followed by a reflex quantitative test if positive (HCV RNA, PCR Qual w/Rfx). A repeat ALT level shall be obtained one month after initial testing if the patient is 45 years old or younger and the initial ALT level was less than two (2) times the normal laboratory value.

4. All inmate-patients shall be informed of their test results by the primary care provider (PCP). If test result is positive for HCV the inmate-patient shall be informed in a face-to-face meeting with the PCP.

5. All inmate-patients who have positive PCR test results shall proceed to Phase II.

6. Phase I terminates and Phase II begins on the date the inmate-patient is informed of his or her positive HCV test result.

7. The anticipated time period for an inmate-patient to complete Phase I is three (3) months.

B. Phase II: Initial Management After Diagnosis of HCV

1. Inmate-patients who have a positive PCR test result shall be followed in the HCV Clinical Management Program and shall have a *Hepatitis C Diagnostic/Pre-Treatment Flow Sheet (Phase I & II)* and a *Hepatitis C Clinical Evaluation Form* initiated. Refer to Attachments E and F.

2. Inmate-patients followed in the HCV Clinical Management Program shall receive a *Hepatitis C Patient Information* handout and *General Instructions for Hepatitis C Patients* handout. Refer to Attachments A and B.

3. Inmate-patients who require vaccination against hepatitis A and/or hepatitis B shall have the vaccination series completed no later than six (6) months after the start of phase II.

4. During the evaluation process possible contraindications to effective therapy shall be assessed since the intent is to enable medically eligible patients to complete a course of monitored therapy, if tolerated. Refer to Attachment C

5. Genotype testing shall be done before consideration for liver biopsy since this impacts eligibility for receiving combination therapy related to remaining length of incarceration time.

6. A liver biopsy shall not be done and combination therapy shall not be started if the patient is expected to be released or paroled before the entire process can be completed. Refer to Attachment C

7. Inmate-patients 45 years old or younger undergoing the initial evaluation shall have three (3) consecutive ALT tests performed at least one month apart and within a period of no greater than three (3) months, unless one of these, or any previous ALT tests, is documented to be two (2) times normal or greater.

8. Inmate-patients 45 years old or younger with ALT levels elevated to less than two (2) times normal laboratory values for all three (3) consecutive ALT tests performed as required in Phase II, Item 7, are not eligible for combination therapy; however, they shall have a repeat ALT test at least once a year.

9. Inmate-patients older than 45 years of age do not require elevated ALT levels to be considered for liver biopsy.

10. Inmate-patients eligible for HCV treatment shall be offered testing for the presence of HIV infection and counseling. Although HIV testing is not mandatory to be considered for a liver biopsy and HCV treatment and although HIV co-infection with HCV is not common among inmate-patients in the CDC system, the presence of HIV sero-positivity may change treatment decisions related to the liver biopsy results and HIV infection.

11. Inmate-patients who previously received appropriate combination therapy for HCV but relapsed, or who did not respond to the therapy are currently not candidates for re-treatment.

12. Inmate-patients who previously received appropriate combination therapy for HCV but have findings consistent with re-infection or indications suggesting current or recent substance abuse are not candidates for re-treatment.

13. Inmate-patients not eligible for combination therapy shall have this decision thoroughly discussed with them by the PCP. If the sole reason for ineligibility is a Time to Parole Exclusion, the PCP shall advise the inmate-patient that if his/her parole date changes, the inmate-patient should file a *Request for Health Care Services* form CDC 7362 for an appointment to inform the PCP of the parole date change. There will be no co-pay charge for this appointment. The discussion of ineligibility shall be documented in the Unit Health Record (UHR).

14. Inmate-patients who do not wish to be treated currently with combination therapy or who are not eligible for combination therapy shall continue to be followed every six (6) to twelve (12) months through the HCV Clinical Management Program and advised of new treatment options, as they become available. Inmate-patients who are paroling shall receive Attachment M and a copy of Attachments E and F.

15. A referral to an appropriate medical specialist and/or the Medical Authorization Review (MAR) HCV Sub-committee may be considered for inmate-patients with issues regarding treatment eligibility or clinical management.

16. Once counseling has been provided documentation of the discussion shall be recorded in the UHR and the various steps in the diagnostic and therapeutic process shall be documented using the form shown in Attachment E.

17. To qualify for a liver biopsy and combination therapy an inmate-patient's parole date shall occur at least *10 or 16 months* from the time the PCP refers the patient for a liver biopsy by completing the *Request for Services* form CDC 7243, depending on genotype. Inmate-patients with genotype 2 or 3 with less than *ten (10) months* to parole from the time the PCP refers the patient for a liver biopsy by completing the *Request for Services* form CDC 7243, and inmate-

patients with genotype 1, 4 or 6 with less than *sixteen (16) months* to parole from the time the PCP refers the patient for a liver biopsy by completing the *Request for Services* form CDC 7243 do not qualify for biopsy and combination therapy.

18. Inmate-patients eligible for HCV treatment shall have the following issues discussed: the reasons and requirement for a liver biopsy; the requirement for a signed treatment contract; possible medical therapies; possible side effects related to treatment, and treatment success rates. Refer to Attachment A and D.

19. Inmate-patients who agree to treatment shall have signed contracts in their UHR in order to proceed to Phase III. Refer to Attachment G.

20. At the time the inmate-patient signs the HCV biopsy and treatment contract, the PCP shall refer the inmate-patient for a liver biopsy by completing a *Request for Services* form CDC 7243.

21. Except for those inmate-patients 45 years old or younger with ALT levels elevated to less than two (2) times normal laboratory values during testing required in phase II section 8, the anticipated time period for an inmate-patient to complete Phase II is two (2) months. This excludes the hepatitis A and/or hepatitis B vaccination process as it may take up to six (6) months to complete the series.

C. Phase III: Staging by Liver Biopsy and Combination Therapy

1. Inmate-patients being considered for liver biopsy shall have their cases reviewed by the MAR HCV Sub-committee.

2. Inmate-patients referred to the MAR HCV Sub-committee shall have had a *Hepatitis C Diagnostic/Pre-Treatment Flow Sheet* and a *Hepatitis C Clinical Evaluation Form* completed prior to the referral. Refer to Attachments E and F.

3. The MAR HCV Sub-committee may request that the PCP obtain additional consultations or studies prior to approval for a liver biopsy.

4. Inmate-patients referred to the MAR HCV Sub-committee shall have a thorough review of their mental health history documented in the UHR by a mental health clinician. Refer to Attachment H.

5. Inmate-patients who are otherwise eligible for a liver biopsy and agree to a liver biopsy and have a signed *Biopsy and Treatment Contract* shall have a liver biopsy approved and scheduled.

6. Inmate-patients approved for liver biopsy shall have a medical hold placed on them to prevent transfer until the liver biopsy has been completed and the decision to begin combination therapy has been made based on the biopsy results.

7. In general, the liver biopsy should be completed within three (3) months from the time the PCP requests that a liver biopsy be performed by completing the *Request for Services* form CDC 7243.

8. Inmate-patients who have had a liver biopsy shall have their cases reviewed by the MAR HCV Sub-committee prior to initiation of combination therapy.

9. Inmate-patients whose liver biopsy results are consistent with stage 2-3 fibrosis or greater, and who otherwise meet inclusion criteria will be offered combination therapy as shown in Attachment J.

10. Patients that are HIV-infected, whose liver biopsy results are consistent with stage 2 fibrosis or greater, and who otherwise meet inclusion criteria are also eligible for combination therapy.

11. Inmate-patients whose liver biopsy results are consistent with stage 2 fibrosis or less, and inmate-patients who are HIV infected and whose liver biopsy results are consistent with less than stage 2 fibrosis, are currently not eligible for combination therapy, but shall be followed every six (6) to twelve (12) months in the HCV Clinical Management Program and reconsidered for liver biopsy every four (4) years.

12. If there are questions of eligibility regarding liver biopsy or combination therapy, the PCP working through the MAR HCV Sub-committee may submit a request for consideration for review and decision to the Health Care Review Sub-committee.

13. The anticipated time period from the HCV screening request made by the inmate-patient to the initiation of combination therapy is nine (9) months, except for patients 45 years old or younger with ALT levels elevated to less than two (2) times normal during testing required in phase II section 8.

14. Inmate-patients receiving combination therapy shall be seen by the PCP weekly for the first two weeks and monthly thereafter beginning with the fourth (4) week.

15. Inmate-patients receiving combination therapy shall have appropriate evaluations and laboratory tests as outlined in Attachments I, J, K1 or K2.

16. Inmate-patients in the Mental Health program who are receiving interferon may be seen on a more frequent basis as determined by the interdisciplinary treatment team.

17. Assuming treatment is well-tolerated (see #20 and #21), inmate-patients with genotype 2 or 3 complete a six (6) month course of combination therapy, and PCR testing at three (3) months is not needed.

18. Inmate-patients with genotype 1, 4 or 6 who are receiving combination therapy shall have a quantitative PCR test performed after the first three (3) months of therapy to determine response. Those who achieve more than a 2-log reduction in viral titer at 3 months are considered "responders." Those whose viral titer at three (3) months remains within two (2) logs of the pre-treatment value are considered "non-responders." Inmate-patients with genotype 1, 4 or 6 who are non-responders at three (3) months shall have combination therapy discontinued

19. Assuming treatment is well-tolerated (see #20 and #21) inmate-patients with genotype 1, 4 or 6 who are responders to combination therapy at 3 months shall continue therapy for an additional nine (9) months to complete a total of twelve (12) months.

20. Inmate-patients who develop clinical complications while receiving combination therapy shall be evaluated and if deemed appropriate, combination therapy may be adjusted or discontinued. Refer to Attachment L.

21. Inmate-patients who develop neuropsychiatric complications while receiving interferon shall be referred immediately for a mental health evaluation and the designated mental health professional shall be contacted. If deemed appropriate, combination therapy may be adjusted or discontinued.

22. The decision to discontinue or adjust combination therapy may be discussed with the MAR HCV Sub-committee, or an appropriate specialist.

23. All inmate patients who complete combination therapy (6 months for genotypes 2 and 3; 12 months for responders with genotypes 1,4, and 6) will be tested for the presence of HCV with a qualitative PCR with reflex quantitative PCR to assess response.

24. "Responders" to combination therapy shall continue in the HCV Clinical Management Program after treatment is completed in order to document long-term remission for twelve (12) months or until parole. This will assist in program evaluation.

25. "Non-responders" to combination therapy shall continue to follow-up in the HCV Clinical Management Program at least every twelve (12) months and will be advised of new treatment options, as they become available.

26. Inmate-patients with a documented history of stage 4 fibrosis or clinical cirrhosis shall have an alpha fetoprotein level checked every six (6) to twelve (12) months to screen for hepatocellular carcinoma.

27. Inmate-patients with elevated alpha fetoprotein may be considered for a CT scan, sonogram, and/or referral to an appropriate specialist.

28. Inmate-patients who have received a liver biopsy and combination therapy who are paroling shall receive a copy of Attachments E, F, K1 or K2 and M.

29. The Utilization Management (UM) Nurse will track the baseline viral load utilizing the UM Database for inmate-patients who qualify for combination therapy. Additionally, inmate-patients with genotype 1, 4 or 6 receiving combination therapy will have repeat viral load performed after three months of therapy to determine response. Included in the UM Database are the dates and results of pertinent laboratory tests and liver biopsies. Results will be compiled by the UM Nurse and presented to the MAR HCV Sub-committee.

HEPATITIS C
PATIENT INFORMATION

WHAT IS HEPATITIS C?

Hepatitis is any inflammation of the liver. The most common causes of liver inflammation are viruses, drugs, and alcohol. *Hepatitis C* is one of the viruses which may cause liver inflammation or hepatitis.

HOW IS IT SPREAD?

Hepatitis is most commonly acquired from contaminated needles (including tattooing needles), snorting drugs, using shared paraphernalia, or from a blood transfusion prior to 1990. Other risk factors for hepatitis C include hemodialysis or job exposure to human blood. At the present time, there is no vaccine to prevent hepatitis C infection.

DIAGNOSIS

Most people with the infection look and feel well and they have usually had the virus for many years before the diagnosis. The infection is usually diagnosed when abnormalities are found on a routine blood test or at the time of blood donation.

After acquiring the hepatitis C virus, the infected individual makes antibodies against the virus (Hepatitis C virus antibodies). These antibodies are detected during screening for hepatitis C. Although disease-specific antibodies usually signify immunity from the disease they attack, in the case of hepatitis C, the antibodies are <u>not</u> protective and having antibodies does not mean the infection has resolved or that the patient is immune. The vast majority of those with hepatitis C virus *antibodies* also carry the virus.

If you have antibody to hepatitis C, you will have a blood test to determine if the hepatitis C virus is present. If you test positive for the virus, you have hepatitis C infection.

After the hepatitis C virus is detected, another important test to perform is the viral genotype. Genotypes are subgroups of the virus sharing genetic properties. The various genotypes of hepatitis C have different behaviors and respond differently to treatment. Hepatitis C genotypes 1, 2, 3, and 4, are the most common. Genotypes 2 and 3 are the most responsive to treatment.

WHAT DOES THE HEPATITIS C VIRUS DO?

You cannot live without your liver. It removes drugs from your system and it produces many essential products, including cholesterol, proteins, and clotting factors. The hepatitis C virus inhabits liver cells and causes inflammation. Over time, this ongoing inflammation injures the structure and function of the liver cells. In most persons, this is typically a very slow process. Only some (10 to 20 percent) of persons with hepatitis C go on to develop serious liver injury, and in those persons, it takes many years (10 to 40). Alcohol use will cause any person with hepatitis C to develop more rapid and severe liver injury. In those persons with advanced hepatitis C disease, severe liver scarring (cirrhosis), and even liver cancer (hepatocellular carcinoma) or failure may occur.

SYMPTOMS

Most people carrying the virus feel well. In those persons in whom the disease progresses, symptoms generally are minimal until the disease is quite advanced. The severity of the disease can be assessed by history and examination, laboratory markers and, most reliably, by liver biopsy. End stage liver disease may result in abdominal swelling (ascites); mental confusion (encephalopathy); bleeding from the esophagus or stomach due to varices (enlarged veins); liver cancer; or other serious complications.

TREATMENT

If repeated blood tests show the liver is functioning differently than normal, a liver biopsy may be performed. This test is done in a clinical setting, and the patient generally does not stay for more than a few hours to be observed after the biopsy is completed. It requires using a special needle to pierce the skin and obtain a small piece of the liver for microscopic examination, to determine the degree of liver damage. This is one of the most important factors in deciding whether drug treatment for the hepatitis C virus might be offered.

At present, there are only a few drugs available to treat hepatitis C. The course of therapy is long and must be uninterrupted to get the maximum chance for cure. It is typically associated with some unpleasant side effects, although many can be managed with physician monitoring and medication adjustments. With this therapy, about 50 to 60 percent of patients clear the infection and are considered cured. However, a person can still be re-infected if re-exposed to hepatitis C. There is no evidence that treatment administered at the last stages of HCV significantly reduces the effectiveness of the drug treatment. Currently there are no studies to show that therapy actually increases the lifespan or reduces the already low risk of developing cirrhosis or cancer.

GENERAL INSTRUCTIONS FOR HEPATITIS C PATIENTS

- **AVOID USE OF ALCOHOL**
- **DO NOT USE INJECTION DRUGS**
- **DO NOT "SNORT" DRUGS**
- **DO NOT GET ANY ILLEGAL TATTOOS**
- **DO NOT SHARE YOUR TOOTHBRUSH, RAZOR, OR OTHER PERSONAL CARE ITEMS**
- **REDUCE WEIGHT IF OVERWEIGHT**
- **EAT A WELL-BALANCED HEART HEALTHY DIET**
- **DRINK PLENTY OF FLUIDS**
- **GET ADEQUATE REST AND REGULAR EXERCISE**
- **STOP SMOKING**
- ***ASPIRIN* AND *IBUPROFEN (MOTRIN, ADVIL)* SHOULD BE USED WITH EXTREME CAUTION AND ONLY AFTER DISCUSSION WITH YOUR PHYSICIAN**
- **YOU MAY USE *ACETAMINOPHEN (TYLENOL)* FOR PAIN OR OTHER *ACETAMINOPHEN* CONTAINING MEDICATIONS, BUT THE DOSE SHOULD NOT EXCEED 4 GRAMS PER DAY. CHRONIC USE SHOULD BE AVOIDED**
- **AVOID TAKING SUPPLEMENTAL IRON**
- **DO NOT DONATE BLOOD, TISSUE, OR ORGANS**
- **MINIMIZE USE OF PAIN MEDICATIONS, ESPECIALLY NARCOTICS**

Exclusion Criteria for Combination Therapy*

No biopsy or treatment if an early release date: generally less than ten [10] months from the time the primary care provider refers the inmate-patient for a liver biopsy by completing the *Request for Services* form CDC 7243 for genotypes 2 and 3, or less than sixteen [16] months from the time the primary care provider refers the inmate-patient for a liver biopsy by completing the *Request for Services* form CDC 7243 for other genotypes.

- An early release date: generally less than ten [10] months from the time the primary care provider refers the inmate-patient for a liver biopsy by completing the *Request for Services* form CDC 7243 for genotypes 2 and 3, or less than sixteen [16] months from the time the primary care provider refers the inmate-patient for a liver biopsy by completing the *Request for Services* form CDC 7243 for other genotypes
- Poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, blood dyscrasias, seizures, cancer, diabetes mellitus (hemoglobin A_{1c} >8.5%), or renal insufficiency (creatinine >2 mg/dL)
- Inmate-patients 45 years old or younger with ALT levels elevated to less than two (2) times normal laboratory values on three consecutive tests, at least one month apart, are not eligible for treatment
- Decompensated cirrhosis – e.g. albumin <3, jaundice, ascites, varices, coagulopathy
- Autoimmune disease
- WBC <1,500/mm^3, platelets <75,000/mm^3
- Hemolytic anemias, or hemoglobin <11gm/dL or hematocrit <33%
- Solid organ transplantation
- HIV infection w/CD4 Count <300
- Poorly controlled psychiatric/psychological condition
- Serious suicidal behavior in the past 12 months
- History of illicit drug use, alcohol or other substance abuse, or other high risk behaviors currently active or within the past 6-12 months
- Inability to cooperate with treatment
- Inability to give informed consent
- Age >60 years
- Pregnancy – a pregnancy test is required prior to initiating therapy

***Refer to drug manufacturer's warnings in addition to highlighted contraindications**

POTENTIAL SIDE EFFECTS
INTERFERON AND/OR RIBAVIRIN THERAPY

While you are taking interferon and/or ribavirin you may experience some of the side effects listed below. The problem most commonly reported is flu-like symptoms. These symptoms are reduced by taking acetaminophen (Tylenol®) before each interferon injection. Drinking plenty of water and getting adequate rest and exercise also help to minimize ill effects.

- **Injection site inflammation** **
- **Nonspecific flu-like symptoms,** ***such as*****:**
  - **headache**
  - **chills**
  - **fatigue**
  - **fever**
- **Gastrointestinal symptoms,** ***such as*****:**
  - **loss of appetite**
  - **nausea**
  - **vomiting**
  - **diarrhea**
  - **heartburn or indigestion**
- **Psychiatric symptoms,** ***such as*****:**
  - **depression**
  - **insomnia**
  - **anxiety**
  - **irritability**
- **Respiratory symptoms,** ***such as*****:**
  - **cough**
  - **shortness of breath**
- **Skin disorders,** ***such as*****:**
  - **hair loss**
  - **rash**
  - **itching**
  - **dry skin**
- **Blood element problems,** ***such as*****:**
  - **reduced number of white blood cells****
  - **reduction in platelets**
  - **Anemia**
- **Possible birth defects during and for 6 months after completion of therapy**

****Pegylated interferon's most noticeable side effect**

CALIFORNIA DEPARTMENT OF CORRECTIONS HEPATITIS C CLINICAL MANAGEMENT PROGRAM

HEPATITIS C DIAGNOSTIC/PRE-TREATMENT FLOW SHEET (PHASE I & II)

Patient Name:			
CDC Number:			
Date of Birth:		Age:	
PCP:			
Institution:			

DIAGNOSTIC STUDIES						
SEROLOGY	Date	Results				
HEP C antibody						
HEP B antibocy						
HEP A antibody						
HIV (recommended)						
HEMATOLOGY/COAG.	Date	Results				
HgB						
WBC						
Platelet Count						
INR						
CHEM PANEL	Date	Results	Date	Results	Date	Results
ALT						
Albumin						
Bilirubin						
Creatinine						
HCV ANTIGEN	Date	Results				
Qualitative PCR						
Reflex Quantitive PCR						
OTHER	Date	Results				
TSH						
ANA						
Fe/Ferritin						
AFTER ELIGIBILITY ESTABLISHED	Date	Results				
Genotype						
Biopsy						
AFP (as clinically indicated)						

Hepatitis Vaccination Record			
	DATE(S) ADMINISTERED		
INNOCULATION(S)	#1	#2	#3
Hepatitis A			
Hepatitis B			

Do not write in shaded areas.

CALIFORNIA DEPARTMENT OF CORRECTIONS HEPATITIS C CLINICAL MANAGEMENT PROGRAM

HEPATITIS C CLINICAL EVALUATION FORM

Inmate: _____ CDC#: _____ Age: _____ Date: _____

Facility: _____ Unit: _____ ERPD: _____ PCP: _____

Allergies: _____ Genotype: __

HISTORY

REASON FOR VISIT: ☐ Intake ☐ F/U

☐ Other: _____

ASSOCIATED CONCERNS:

Ascites	☐ Yes	☐ No
Bleeding	☐ Yes	☐ No
Chest Pain	☐ Yes	☐ No
Edema	☐ Yes	☐ No
Fatigue	☐ Yes	☐ No
Fever	☐ Yes	☐ No
Mental Status Change	☐ Yes	☐ No
Nausea/Vomiting	☐ Yes	☐ No
Shortness of Breath	☐ Yes	☐ No

Comment/Other: _____

LIVER BIOPSY RESULTS: _____

DIAGNOSTIC/LAB RESULTS: _____

MEDICAL/SURGICAL HISTORY:

Anemia	☐ Yes	☐ No
Autoimmune Disease	☐ Yes	☐ No
Blood Transfusion	☐ Yes	☐ No
Cardiovascular disease	☐ Yes	☐ No
Cirrhosis	☐ Yes	☐ No
COPD/RAD	☐ Yes	☐ No
Diabetes	☐ Yes	☐ No
Encephalopathy	☐ Yes	☐ No
ETOH Use ≥ ____ day	☐ Yes	☐ No
HAV Immune	☐ Yes	☐ No
HBV Immune	☐ Yes	☐ No
IVDU	☐ Yes	☐ No
Seizures	☐ Yes	☐ No
Suicide Attempt	☐ Yes	☐ No
Thyroid Disease	☐ Yes	☐ No
Varices	☐ Yes	☐ No
CDC 115 Violations	☐ Yes	☐ No
Previous HCV Rx	☐ Yes	☐ No

Other: _____

MEDICATIONS:

1. _____ 2. _____

3. _____ 4. _____

REVIEWED:

☐ Old records ☐ Consultant notes

☐ Previous visits/notes ☐ Radiological studies

☐ Diagnostic/lab studies ☐ Prior records ordered__

COMMENTS: _____

PHYSICAL EXAMINATION

Vitals: T _____ RR _____ P _____

BP _____ Wt _____ BMI _____

Skin:	☐ Normal	☐ Abnormal: _____
Neuro:	☐ Normal	☐ Abnormal: _____
Cardiac:	☐ Normal	☐ Abnormal: _____
Lungs:	☐ Normal	☐ Abnormal: _____
Abdomen:	☐ Normal	☐ Abnormal: _____
Extremities:	☐ Normal	☐ Abnormal: _____

Other: _____

Comments: _____

ASSESSMENT

A. Diagnoses:

1. _____
2. _____
3. _____

B. Treatment Contraindications? ☐ Yes ☐ No

If Yes, explain _____

PLAN

MEDICATIONS:

☐ INF ☐ RBV ☐ Lactulose ☐ Spironolactone

☐ Other: _____ ☐ Other: _____

VS CHECK:

☐ Monthly ☐ Quarterly ☐ Other: _____

DIAGNOSTICS/LABS: ☐ ABD U/S ☐ Biopsy

☐ LFTs ☐ CBC ☐ TSH ☐ ANA ☐ AFP

☐ Chem ☐ Iron Studies ☐ PT/INR ☐ HIV

☐ HCV Genotype ☐ HCV Viral Load

☐ Other: _____

VACCINES: ☐ HAV ☐ HBV ☐ Other: _____

DIET ☐ Regular ☐ Other: _____

EDUCATION PROVIDED:

☐ Handouts ☐ ETOH/Drug ☐ Medications

☐ Other (specify): _____

REFERRAL:

☐ MAR HCV Sub-committee

☐ MH Specialist (indicate type): _____

☐ Specialist (indicate type): _____

☐ Other Chronic Care Program: _____

Return to next visit: ☐ 90 days ☐ 30 days ☐ Other __ days

Signature: ☐ MD ☐ DO ☐ NP

Date _____

CALIFORNIA DEPARTMENT OF CORRECTIONS HEPATITIS C CLINICAL MANAGEMENT PROGRAM

HEPATITIS C BIOPSY AND TREATMENT CONTRACT

Treatment of hepatitis C is reserved for those eligible patients who understand the commitment to therapy, will tolerate and comply with the course of treatment, and agree to avoid all activities that may worsen their liver disease, or infect themselves or others with the hepatitis C virus or other bloodborne pathogens. Every patient who is considered for treatment must complete this contract before a liver biopsy is performed and before initiation of therapy.

Patient's Initials

_____ I understand that a medical hold will be placed on me until the liver biopsy is performed and the biopsy results are discussed with me.

_____ I understand that the therapy may be of no benefit to me and that it may not eradicate my hepatitis C infection.

_____ I have been informed that side effects of treatment of hepatitis C may include fatigue, body aches, and other serious side effects that may persist throughout the course of therapy.

_____ I understand that I may be tested for HIV before beginning treatment as the presence of the HIV virus could seriously impact my hepatitis C infection and its treatment.

_____ I understand that the course of therapy may continue for 12-months and that periodic blood testing will be a necessary part of the hepatitis C treatment program.

_____ I understand that treatment for hepatitis C may cause psychiatric side effects, especially depression.

_____ I understand that I must not become pregnant or attempt to impregnate my spouse during my hepatitis C antiviral treatment or for 6 months after cessation of treatment. I understand that I must use two forms of birth control during heterosexual activity during treatment and for 6 months after treatment ends.

_____ I understand that my failure to comply with the therapy or its monitoring may result in discontinuation of therapy.

_____ I understand that alcohol injures the liver and that drinking alcohol is forbidden.

_____ I understand that I must abstain from any activity that permits exchange of body fluids that may transmit the hepatitis C virus or other bloodborne pathogens. This includes tattooing, sexual activity in prison, IV drug use, and intranasal drug use.

_____ I understand that I may be required to undergo random blood or urine testing for substance abuse and that any positive test will result in discontinuation of, or loss of eligibility for, treatment.

_____ I understand that completion of this contract does not guarantee that I will be endorsed for hepatitis C treatment.

_____ My initials above and my signature below signify my understanding of, and agreement to comply with, the requirements enumerated above. I understand that failure to comply may result in loss of eligibility for therapy or discontinuation of therapy in progress.

_____ _____

Inmate Signature Date

_____ _____

Witness Signature Date

cc: Unit Health Record
Inmate

CALIFORNIA DEPARTMENT OF CORRECTIONS HEPATITIS C CLINICAL MANAGEMENT PROGRAM

HEPATITIS C ANTIVIRAL TREATMENT CANDIDATE

PSYCHIATRIC/PYSCHOLOGIC REVIEW

MENTAL HEALTH HISTORY:

Is there any history of psychiatric illness and what are the diagnoses? Discuss cognitive impairment if applicable:

Describe any suicidal ideation and/or attempts in the last 12 months:

Describe compliance with therapeutic programming and medication treatment over the last 12 months:

If inmate-patient is currently enrolled in the Mental Health Program, what is the level of care (ex: CCCMS, EOP) and where are they housed (ex: Ad-Seg EOP, PSU)?

Describe any known usage of recreational drugs and/or alcohol over the last 12 months:

List any current psychiatric medications:

Disposition/Plan: (check appropriate box)

- ☐ No mental health contraindications to HCV treatment
- ☐ Refer for mental health evaluation before HCV treatment decision
- ☐ Refer to Interdisciplinary Treatment Team (IDTT) before HCV treatment decision
- ☐ Other: _____

COMMENTS:

Inmate Patient Name (Print)	CDC#	Date

Evaluator Name and Title (Print)	Evaluator Signature

HEPATITIS C PRACTICE GUIDELINES

The initial HCV evaluation will include:

HISTORY:

- History of present condition
- Current symptoms, including frequency and severity
- Current medications
- Past medical history
- Drug allergies
- Lifestyle factors
- Family history

EXAMINATION:

- Vital signs
- Examination of:
  - ⇒ Skin
  - ⇒ Neurological system
  - ⇒ Head/Neck
  - ⇒ Heart
  - ⇒ Lungs
  - ⇒ Abdomen
  - ⇒ Extremities
- Examination, if clinically indicated, of:
  - ⇒ Pelvis/Rectum
  - ⇒ Other organ systems

ASSESSMENT:

- Diagnoses
- Treatment Contraindications

PLAN:

- Medications
- Vaccinations:
  - ⇒ Hepatitis A
  - ⇒ Hepatitis B
- Laboratory tests:
  - ⇒ CBC
  - ⇒ Hepatitis serology
  - ⇒ If inmate-patient found to have the antibody to HCV obtain a qualitative PCR with reflex to quantitative
  - ⇒ Chemistry panel
  - ⇒ Liver function tests
  - ⇒ TSH
  - ⇒ ANA
  - ⇒ HIV
  - ⇒ Iron, Ferritin
- Laboratory/ Diagnostic studies if clinically indicated
  - ⇒ Abdominal Ultrasound (If cirrhosis is clinically suspected or documented by biopsy)
  - ⇒ Alpha Fetoprotein (If cirrhosis is clinically suspected or documented by biopsy)
  - ⇒ Liver Biopsy (If eligible for combination therapy)
  - ⇒ Genotype (Do **not** need to recheck)
- Education (e.g. nutrition, exercise, alcohol/illicit drug use, medication management, smoking cessation)
- Referral to hepatologist and/or other specialist or Chronic Care Program, as clinically indicated
- Interval to next visit

NOTE: SEND COPY OF PHYSICIAN'S ORDER FOR MEDICATION TO PHARMACY AFTER EACH ORDERS IS SIGNED

Attachment J

Order Date	Time	Problem #	Physician's Orders and Medications (Orders must be dated, timed, and signed)
			Start Peginterferon AlfA-2a (Pegasys) ONCE WEEKLY
			24 weeks *Genotype 2 and 3* and 48 weeks *Genotype 1, 4 or 6*
			180 mcg (1mL)
			RIBAVIRIN DOSING
			GENOTYPE 2 AND 3 - 24 weeks
			2 x 200 mg in AM 2 x 200mg in PM
			GENOTYPE 1, 4 OR 6 - 48 weeks
			<165 lbs 2 x 200mg in AM 3 x 200mg in PM
			>165 lbs 3 x 200mg in AM 3 x 200mg in PM
			Anti Viral Therapy ROUTINE LAB TESTING DURING TREATMENT
			PRE-TREATMENT: Hepatitis Serology, HCV Antibody, HCV quant by PCR, Genotype, CBC, INR, Chem Panel*, TSH, ANA, Fe/Ferritin, Liver Bx, HIV (recommended)
			FIRST WEEK: CBC
			SECOND WEEK: CBC
			FIRST MONTH: CBC, Chem Panel*
			SECOND MONTH: CBC
			THIRD MONTH: ALL GENOTYPES: CBC, TSH, Chem Panel*; GENOTYPE 1, 4, 6 ONLY: HCV QUANT BY PCR
			FOURTH MONTH: CBC
			FIFTH MONTH: CBC
			SIXTH MONTH: ALL GENOTYPES: CBC, TSH, Chem Panel*; GENOTYPE 2, 3 ONLY: HCV QUAL with reflex QUANT BY PCR
			SEVENTH MONTH: GENOTYPE 1, 4, 6 ONLY: CBC
			EIGHTH MONTH: GENOTYPE 1,4,6 ONLY: CBC
			NINTH MONTH: GENOTYPE 1, 4, 6 ONLY: CBC, Chem Panel*, TSH
			TENTH MONTH: GENOTYPE 1, 4, 6 ONLY: CBC
			ELEVENTH MONTH: GENOTYPE 1, 4, 6 ONLY: CBC
			TWELFTH MONTH: ALL GENOTYPES: HCV QUAL with reflex QUANT BY PCR GENOTYPE 1, 4, 6 ONLY: CBC, TSH, Chem Panel*
			EIGHTEENTH MONTH: GENOTYPE 1, 4, 6 ONLY: HCV QUAL WITH REFLEX QUANT BY PCR
			* Chem Panel must include ALT, bilirubin, albumin, and creatinine

ALLERGIES	INSTITUTION	ROOM

CDC NUMBER, NAME (LAST, FIRST, MI)

Confidential
client information
See W I Code, Sections 4514 and 5328

PHYSICIAN'S ORDERS

DOB: TBCODE:
REL_DATE: