

HEPATITIS C POLICY

This policy is not intended to delineate all the aspects of the care of an offender with hepatitis C. In particular, the minimal requirements in this policy are intended only to help gather necessary information for a provider to make appropriate clinical decisions about the management of each patient. In addition, please be aware that the guidelines listed below are subject to change based on new information as it becomes available.

**POLICY:** To provide guidance regarding the modes of transmission, screening, prevention, initial evaluation, clinical management, evaluation during treatment, housing, and work assignments of offenders with Hepatitis C (HCV).

**PROCEDURES:**

- I. Hepatitis C is transmitted primarily by blood.
  - A. Injection drug use (e.g., sharing needles, syringes, or intranasal devices)
  - B. Needlestick injuries
  - C. Perinatal transmission (e.g., birth to HCV-infected mother)
  - D. Sharing personal items contaminated with blood such as razors or toothbrushes
  - E. Unprotected sex
  - F. Sharing instruments used for body piercings and body art (e.g., tattooing in an unregulated setting)
  - G. Receipt of blood transfusions prior to 1992 and the use of advanced screening tests for hepatitis.
  - H. Use of clotting factors prior to 1987
  
- II. Screening
  - A. All offenders should be evaluated for the above listed risk factors for hepatitis C. On the initial intake physical examination, signs and symptoms of liver disease should be screened. If any risk factors, signs, or symptoms are present, hepatitis C screening with an anti-HCV antibody test should be offered.
  - B. All offenders born between 1945 and 1965 should be tested irrespective of their risk factors. Those who are born within these dates are 5 times more likely than other adults to be infected with hepatitis C.
  - C. Offenders diagnosed with chronic hepatitis B or HIV infection must be tested for hepatitis C as part of the baseline evaluation of these conditions.
  - D. Offenders with persistently abnormal alanine aminotransferase levels (ALT).
  - E. Offenders who have ever received hemodialysis.
  - F. Screening with anti-HCV antibody test should also be performed after an exposure, according to Infection Control Manual Policy 14.06, and whenever clinically indicated.
  - G. Offenders may be tested for anti-HCV antibody once every 12 months at their request. They do not have to disclose any high risk behavior to qualify for testing.

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III. Prevention

- A. Educate staff and offenders about the modes of transmission, prevention, and early reporting of signs and symptoms of infection.
- B. Discourage high risk behaviors including sharing tattooing equipment, unprotected sex, sharing needles, and sharing personal grooming items such as razors, toothbrushes and tweezers.
- C. Any identified needle sharing contacts should have an anti-HCV antibody test. If it is negative, repeat the test in 6 months. There is no post-exposure preventive treatment recommended for hepatitis C.

IV. Testing sequence for identifying current HCV infection

- A. HCV antibody testing cannot distinguish between patients whose past HCV infection has resolved and those who are currently (acute or chronic) HCV infected.
- B. HCV RNA in the blood is a marker for HCV viremia and is detected only in patients who are currently infected.
- C. Patients with reactive (positive) results after HCV antibody testing should be evaluated for the presence of HCV RNA in their blood.
- D. There is no diagnostic need to obtain HCV RNA for existing patients already diagnosed with chronic hepatitis C.

Table: Interpretation of Test Results (adapted from CDC)

Test outcome	Interpretation	Action
HCV antibody nonreactive	No HCV antibody detected	<ul style="list-style-type: none"> <li>• Sample can be reported as nonreactive for HCV antibody. No further action required.</li> <li>• If recent HCV exposure in person tested is suspected, test for HCV RNA.*</li> </ul>
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive and HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and enroll patient in chronic care clinic.
HCV antibody reactive and HCV RNA not detected	No current HCV infection	<ul style="list-style-type: none"> <li>• No further action required in most cases.</li> <li>• In certain situations follow up with HCV RNA testing and appropriate counseling.§</li> <li>• If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay.</li> </ul>

\* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate sero-conversion. If the person tested is immunocompromised, consider testing for HCV RNA.

§ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

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- V. Baseline evaluation and initial management of offenders newly identified as having current HCV infection.
- A. Take a targeted history to determine the probable date infection was acquired. For example, the date of infection in an injection drug user would be the year he started sharing needles. Also obtain history of previous and present alcohol use, co-infection such as HIV or HBV, drug use, symptoms of liver disease, and previous treatment for HCV.
  - B. Perform a physical examination and clinical evaluation looking for signs of advanced liver disease, evidence of other causes of liver disease such as Wilson's disease, and extra-hepatic manifestations (e.g., leukocytoclastic vasculitis, cryoglobulinemia, porphyria cutanea tarda, membranoproliferative glomerulonephritis and type 2 diabetes) of hepatitis C.
  - C. Obtain the following baseline laboratory tests:
    - 1. CBC with differential and platelet count
    - 2. Prothrombin time and INR
    - 3. ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine (these laboratory tests are contained in CMP)
    - 4. HIV
    - 5. anti-HBsAb, anti-HBc total antibody, HBsAg, and anti-HAV total antibody
  - D. Evaluate and offer preventive healthcare measures as clinically indicated.
    - 1. Vaccinate the offender against hepatitis B if all hepatitis serum markers are negative.
    - 2. Vaccinate against hepatitis A if the anti-HAV test is negative.
  - E. Educate the patient about transmission of HCV, obligation to avoid infecting others, the natural history of HCV infection, effect of alcohol and other hepatotoxins on disease, etc.
- VI. Follow-up after the baseline evaluation
- A. Patients with HCV infection must be enrolled in chronic care clinic and seen at least once every 12 months.
  - B. Patients identified as currently HCV infected and enrolled in chronic care clinic may be discharged from chronic care clinic, if baseline transaminases and liver function tests are all within normal limits. Consider obtaining one or more HCV RNA, ALT, and AST tests over 6 months to confirm or rule out current infection. If the ALT and AST results are all within normal limits and at least two negative HCV RNA results at least 6 months apart have been obtained, the patient can be diagnosed with resolved HCV and discharged from follow-up after appropriate counseling about the possibility of future re-infection if high risk behavior is repeated.

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- C. Annual evaluation must include clinical evaluation for signs or symptoms of liver disease, laboratory testing and calculation of AST/Platelet Ratio Index (APRI).
1. Laboratory tests:
    - ALT, AST, bilirubin, albumin (these laboratory tests are contained in CMP)
    - CBC with differential and platelets
    - PT and INR
  2. APRI score: The APRI score must be calculated based on the current AST and platelet count using the formula below  
  
$$\text{APRI} = ((\text{AST} \div \text{ULN}) \div (\text{platelet count})) \times 100$$
  
  
Where ULN = upper limit of normal for the AST level and platelet count is in 1,000/mm<sup>3</sup>  
  
An APRI score calculator is available on CMCWEB under the Tools submenu and is available in the EMR under Guidelines.
  3. APRI score should be recorded in results entry in the EMR.
- D. If the patient has evidence of compensated or decompensated cirrhosis, follow-up as indicated under Advanced Liver Disease, below.
- E. Determine if the offender is a candidate for referral to a designated provider or clinic to be evaluated for possible treatment of HCV.
- A. Co-infection with HIV or hepatitis B is not a contraindication to antiviral therapy. These patients should be considered for referral and evaluation for possible treatment if the APRI is > 0.7.
  - B. Compensated cirrhosis (low albumin but  $\geq 3.0$ , low platelet count but  $\geq 70,000$ , elevated bilirubin but <2.0, and/or prolonged prothrombin time less than 2 seconds greater than control) is not a contraindication to antiviral treatment. These patients should be evaluated for treatment even if their APRI score is less than 0.7 as they may be approaching the point where antiviral treatment is contraindicated because of advanced liver disease.
  - C. Although patients with APRI scores  $\leq 0.7$  generally do not require evaluation for possible treatment, the provider may consider referral if they believe the patient may be a candidate for treatment. Clinical considerations could include
    - a. History suggesting that infection was acquired many years previously.
    - b. Clinical or laboratory evidence of a failing liver.
    - c. Co-morbid conditions that might cause elevation of the platelet count or unusually low AST levels, giving an unreliable APRI score.

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- D. If the APRI is  $> 0.7$  the patient should be considered for referral to a designated HCV clinic or provider to be evaluated for possible treatment of HCV.
    - a. Almost all offenders with an APRI score over 0.7 should be referred, but the decision must be individualized. Considerations that may lead to a decision not to refer could include the patient not wanting treatment, presence of a contraindication to the treatment, or presence of comorbidity that is likely to be fatal before hepatitis C becomes symptomatic. This list is not exhaustive.
    - b. If not already done so, AFP should be ordered by the primary care provider at the time of referral.
    - c. If a patient with an APRI score  $> 0.7$  is not referred, the rationale for not referring must be documented in the medical record.
  - F. If treatment is not initially recommended, the offender should be followed in chronic care clinic and evaluated periodically to determine if treatment should be reconsidered.
  - G. Offenders who enter TDCJ on drug treatment for hepatitis C must have that treatment continued unless the provider documents that it must be discontinued for medical reasons. The patient should be referred to designated HCV clinic or provider for management.
- VII. Evaluation prior to treatment (To be done by the Virology HCV Treatment Team in the UTMB Sector or per Utilization Management process for Texas Tech Sector)
- A. Obtain the following laboratory tests if not done in the preceding 6 months: ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine, CBC with differential, platelets, PT, INR, TSH, serum iron, TIBC, and ferritin.
  - B. Obtain the following laboratory tests (equivalent to LEV2 in EMR): HCV RNA, HCV genotype, alpha-fetoprotein, alpha-1 antitrypsin, ceruloplasmin, ANA, pregnancy test.
  - C. Obtain previous HCV treatment history and outcome to therapy.
  - D. Obtain chest x-ray and EKG if over 40, preexisting cardiac disease is present, or as clinically indicated.
  - E. Obtain A1C if diabetic.
  - F. Obtain liver imaging studies as clinically indicated.
  - G. If eligible for peginterferon based therapy
    - 1. Visual acuity should be performed at baseline. Funduscopy examination should be performed in patients at higher risk for retinopathy including patients with a history of ophthalmologic disorder, hypertension, diabetes, and older patients (age  $> 50$  years).
    - 2. Mental health evaluation
  - H. Prior to initiating treatment, providers must distribute patient education materials and obtain informed consent. Informed consent must be documented in the patient's

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medical record. If the patient chooses no treatment, the provider must document such in the medical record including the reason(s) stated by the patient.

- I. Current treatment options have limitations. Risk and benefits of beginning, delaying or deferring treatment should be evaluated and weighed carefully.
  1. Treatment is not recommended if the offender has contraindication(s) to therapy.
  2. Treatment generally is not recommended if the offender has insufficient time left in the system to complete work-up, treatment and follow up evaluation of sustained virologic response. Time left in the system may be determined by viewing the maximum expiration date (max exp date) on the assignment screen in the TDCJ mainframe computer.
  3. Treatment generally is not recommended if there is evidence that the offender is participating in high risk behavior.
  4. Treatment generally is not recommended if the offender is poorly compliant with pretreatment work-up or refuses treatment.
  5. Treatment is generally not recommended for patients with a limited life expectancy ( $\leq 12$  months) because benefits of therapy are unlikely.
  6. Treatment is generally not recommended if the offender has decompensated cirrhosis, but may be considered on a case-by-case basis.
  7. Treatment is generally not recommended if the offender has hepatocellular carcinoma and treatment is not potentially curative.
  8. Treatment is generally not recommended and delayed for an offender with no or mild fibrosis (FO-F2) since decompensated cirrhosis is unlikely to develop in the subsequent few years. Waiting for newer therapies is prudent.
  
- VIII. Housing while on treatment
  - A. Patients treated with antiviral therapy should be housed at the designated unit (i.e., Center of Excellence) where medical services are offered  $\geq 16$  hours per day.
  - B. Patients treated with antiviral therapy must also be placed on a medical hold while on drug therapy.
  
- IX. Job Assignments
  - A. Offenders with chronic hepatitis C should be restricted from plumber's helper or bar trap cleaner job assignments unless they have been vaccinated against hepatitis A or have been documented to have positive anti-HAV antibody.
  - B. Restrictions for other job assignments will be handled on a case by case basis.
  - C. Job restrictions will be entered onto the HSM-18.
  
- X. Reporting
  - A. Anti-HCV and HCV RNA positive offenders must be reported to the Office of Public Health within 7 days.

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- B. If the patient has had a documented seroconversion to HCV positive, or has clinical signs and symptoms of acute hepatitis or has ALT > 5 times higher than the upper limit of normal, report the case as acute hepatitis C.
- C. Enter the mainframe medical alert code 7054 on HCV positive offenders.

### XI. Advanced Liver Disease

- A. Patients with evidence of compensated or decompensated cirrhosis must be enrolled in chronic care clinic. They must have bilirubin, creatinine (bilirubin and creatinine part of CMP), and INR—done every 6 months in addition to any laboratory tests that are clinically indicated. They should be screened for hepatocellular carcinoma every 6 months with ultrasound.
- B. Evaluation of patients with cirrhosis should include clinical evaluation for signs or symptoms of hepatic encephalopathy and ascites.
  - 1. Hepatic encephalopathy is a clinical diagnosis and ordinarily, serum ammonia levels are unnecessary. Ammonia levels are often falsely elevated if the serum specimen is not handled properly or is not immediately delivered to the lab. Prevention or treatment with lactulose should be considered.
  - 2. If the patient has ascites or esophageal varices, consider the use a beta blocker to treat portal hypertension.
- C. Screening for hepatocellular carcinoma should include a liver ultrasound every 6 months. An alternative imaging study may be considered if clinically indicated.
- D. Patients with cirrhosis are in the high risk groups that must be offered influenza and pneumococcal vaccines according to Infection Control Manual Policy B-14.07.
- E. For patients with decompensated cirrhosis, discuss prognosis of their illness and their treatment preferences, obtaining an advance directive when appropriate.
- F. Consider referring patients with decompensated cirrhosis to Gastroenterology to be evaluated for possible referral to be considered for liver transplant. The decision to refer a patient must be made on a case by case basis.
- G. At each chronic care visit, calculate the Model for End-stage Liver Disease (MELD) score. A patient with a MELD score of 30 or greater (associated with a 52% risk of mortality within 3 months) should be referred to a hospice unit if the patient agrees to the conditions of hospice placement, or considered for referral to be evaluated for liver transplant if that has not already been done. An individual should not be accepted for or denied hospice care solely on the basis of his/her MELD score, however. The MELD score can be calculated online at:

<http://www.unos.org/resources/MeldPeldCalculator.asp?index=98>

A MELD score calculator is also available on CMCWEB under the Tools submenu and is available in the EMR under Guidelines.

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The MELD formula is also given below:

$$\text{Risk Score} = 10 * ((.957 * \ln(\text{Creat})) + (.378 * \ln(\text{Bili})) + (1.12 * \ln(\text{INR}))) + 6.43$$

Where

- $\ln$  means the natural logarithm (base  $e$ )
- For any lab values  $< 1$ , use the value 1 in the formula
- If creatinine is  $> 4$ , use the value 4
- If the patient has been dialyzed 2 or more times in the previous week, use the value 4 for creatinine
- The risk score should be rounded to the nearest integer
- This formula only applies to adults

- H. Every patient with decompensated cirrhosis with a MELD score over 22, recurrent ascites, recurrent bleeding esophageal varices, or recurrent hepatic encephalopathy should be referred for MRIS (Medically Recommended Intensive Supervision).
- I. Patients who are not able to take care of themselves in general population such as patients that have a history of episodic hepatic encephalopathy, bleeding esophageal varices, massive edema, or massive ascites should be considered for hospice care, sheltered housing, or assisted living.

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Hepatitis Reporting Form

**This form is for reporting purposes only and is not intended as a clinical guideline.**

Name: \_\_\_\_\_ TDCJ Number: \_\_\_\_\_

Facility: \_\_\_\_\_ UH Number: \_\_\_\_\_

Diagnosis:

- |                          |                   |  |                     |
|--------------------------|-------------------|--|---------------------|
| <input type="checkbox"/> | Acute Hepatitis A |  |                     |
| <input type="checkbox"/> | Acute Hepatitis B |  | Chronic Hepatitis B |
| <input type="checkbox"/> | Acute Hepatitis C |  | Chronic Hepatitis C |

Supporting Data:

Symptoms (acute disease only): \_\_\_\_\_ Date of Symptom Onset: \_\_\_\_\_

- Nausea, vomiting or anorexia
- Diarrhea
- Jaundice or icterus
- Fever, malaise, flu-like symptoms

Lab: (lab tests done are based on clinical considerations and should not be ordered simply to complete this report form.)

Test	Date, if done	Pos	Neg	Not Done or Unknown
<b>Acute Hepatitis A</b>				
Hep A antibody (anti-HAV IgM Ab)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Hepatitis B</b>				
Hep B surface antigen (HBsAg)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hep B core antibody (anti-HBc IgM Ab)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hep B surface antibody (anti-HBs Ab)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Hepatitis C</b>				
Hep C antibody (anti-HCV Ab)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HCV RNA	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Hepatitis D</b>				
Delta hepatitis antibody (anti-HDV Ab)	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**\*For Acute Illness only:**

Highest\* ALT (SGPT) level: \_\_\_\_\_ Date: \_\_\_\_\_

Highest\* AST (SGOT) level: \_\_\_\_\_ Date: \_\_\_\_\_

Expected Serological Patterns					
Acute Hepatitis A	Resolved Hepatitis A (not reportable)	Acute Hepatitis B	Chronic Hepatitis B	Resolved Hepatitis B (not reportable)	Hepatitis C
Anti-HAV IgM (+)	Anti-HAV IgM (-) Anti-HAV IgG (+)	HBsAg (+) HbeAg (+) Anti-HBc IgM (+)	HBsAg (+) HBeAg (+ in majority) Anti-HBc total (+) Anti-HBc IgM (-)	HBsAg(-), HBeAg(-) Anti-HBs (usually +) Anti-HBc total (usually +)	Anti-HCV (+) HCV RNA (+)

## Consent and Treatment Contract for Chronic Hepatitis C

I, \_\_\_\_\_, have requested treatment for chronic hepatitis C infection after discussing my medication condition and treatment options with the provider.

## Initial

<input type="checkbox"/>	I understand my medical condition and why treatment is being recommended. It was explained to me in a language that I understand and I have no additional questions at this time.
<input type="checkbox"/>	I understand that I may ask questions at any time during treatment.
<input type="checkbox"/>	I understand that even if I receive treatment my condition may not be cured.
<input type="checkbox"/>	I understand that treatment may reduce my risk of developing cirrhosis or other complications of hepatitis in the future if I am one of those who respond to treatment.
<input type="checkbox"/>	I understand that treatment may continue for 12 or 24 weeks and requires frequent visits to the medical department for clinic appointments, blood tests, medication injections, and medication administration. Visits are essential to achieve safe and successful treatment results and to prevent the hepatitis C virus from becoming resistant to medications.
<input type="checkbox"/>	I understand that I must show up for peginterferon injections and that injections are given in the medical clinic or other location(s) designated by medical staff. I understand that injections may be given early in the morning.
<input type="checkbox"/>	I understand that I must go to the medical department to take ribavirin, sofosbuvir, or ledipasvir/sofosbuvir if I am prescribed them as part of combination therapy.
<input type="checkbox"/>	I will take my medication as directed by the provider. I understand that I must notify the provider if I miss or stop taking doses of medication.
<input type="checkbox"/>	I understand that medications may be discontinued if I am not taking them regularly (i.e., missed doses) or if I miss clinic appointments or laboratory tests.
<input type="checkbox"/>	I understand that the provider may stop my medications if it is not working or if I experience serious and/or too many side effects.
<input type="checkbox"/>	I understand that I may be tested for illicit drug use any time while I am on medication for hepatitis C and I agree to that testing. I understand that it is important to abstain from illicit drug use to prevent reinfection with hepatitis C.
<input type="checkbox"/>	I understand that it is important to abstain from sexual activity and unprotected sex to prevent reinfection with hepatitis C.
<input type="checkbox"/>	I understand that ribavirin can cause birth defects and that I should not be sexually active, become pregnant, or father a child while on treatment. Both women and men, especially those close to release, should avoid sexual activity during treatment and 6 months after treatment is complete if I am not using 2 forms of birth control including a condom.
<input type="checkbox"/>	I understand that it is important to abstain from body piercing or tattooing to prevent reinfection with hepatitis C.
<input type="checkbox"/>	I understand that medications will be discontinued if any drug screen is positive or if I have a disciplinary case for drug use, body piercing, and sexual intercourse.
<input type="checkbox"/>	I understand that even if the hepatitis C antiviral therapy is successful in eliminating the virus, if I engage in behaviors such as injecting drug use, tattooing, inhaling cocaine, or having unprotected sex that I may become re-infected with hepatitis C.

<input type="checkbox"/>	I understand that there are certain medications that may interact with medications used to treat hepatitis C and that the provider must be aware of all medications that I take including medications bought through the Commissary. It is my responsibility to inform the provider of all medications that I buy through the Commissary.
<input type="checkbox"/>	I understand treatment for hepatitis may have serious side effects some of which can lead to death, including but not limited to, flu-like symptoms, worsening of liver inflammation, anemia, allergic reaction, , severe rash, heart attack, severe depression, suicide, infections, loss of vision, and thyroid disease.
<input type="checkbox"/>	I understand that I should immediately report severe side effects to the provider.
<input type="checkbox"/>	I understand that if sofosbuvir or ledipasvir/sofosbuvir is discontinued it may not be restarted due to the high potential for virus resistance.
<input type="checkbox"/>	I understand that I may stop taking medication at any time by contacting the provider. However, I understand that discontinuing medication and treatment may result in failure to control the development of progressive liver disease.
<input type="checkbox"/>	I understand that I may be moved to a designated hepatitis C treatment prison unit while I'm taking antiviral medications to ensure continuity of care, to minimize the risk of missed doses of medication, and to increase my chances of successfully completing treatment.
<input type="checkbox"/>	I understand that I will be placed on a medical hold that prevents me from being transferred to another prison unit while I'm taking antiviral medications to ensure continuity of care, to minimize the risk of missed doses of medication, and to increase my chances of successfully completing treatment.
<input type="checkbox"/>	I understand that I may withdraw this consent in writing at any time.
<input type="checkbox"/>	I understand that I will receive the medications listed below to treat my hepatitis C infection (health care provider check all that apply). <input type="checkbox"/> Peginterferon <input type="checkbox"/> Ribavirin <input type="checkbox"/> Sofosbuvir <input type="checkbox"/> Ledipasvir/Sofosbuvir

I, \_\_\_\_\_, certify that I have read and understand the information above and  
(Print Name)  
hereby consent to treatment.

\_\_\_\_\_  
Offender Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
TDCJ #

\_\_\_\_\_  
DOB

Patient given "Patient Education Information Chronic Hepatitis C Treatment" handout

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Print Witness Full Name

\_\_\_\_\_  
Witness Title

\_\_\_\_\_  
Date