



Department of Public Safety and Correctional Services

Office of the Secretary

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INMATE GRIEVANCE OFFICE

July 18, 2007

The Honorable Ulysses Currie
Chairman, Senate Budget and Taxation Committee
3 West, Miller Senate Building
Annapolis, Maryland 21401-1991

The Honorable Norman H. Conway
Chairman, House Committee on Appropriations
1312 Whittier Drive
Salisbury, Maryland 21801-3241

RE: Joint Chairmen's Report on Hepatitis C Treatment in DPSCS

Dear Senator Currie and Delegate Conway:

On page 146 of the 2007 Joint Chairmen's Report, the following information is requested of the Department of Public Safety and Correctional Services:

Provided that \$100,000 of this appropriation may not be expended until the Department of Public Safety and Correctional Services (DPSCS) submits a report by July 1, 2007 to the House Appropriations Committee, the Health and Government Operations Committee, Senate Budget and Taxation Committee, and the Senate Education, Health and Environmental Affairs Committee on the progress that has been made in Hepatitis C prevention and treatment within the correctional system. Specifically, this report shall include their methodology, the number of inmates that have been tested, educated and treated in the last three years, and their planned goals and strategies for Hepatitis C Virus diagnosis, education and treatment for the next three years.

Please accept my apology for the lateness of this report. It was due on July 1, 2007, and is therefore, 17 days late. I hope that will not interfere with the release of the associated funds for this Joint Chairmen's Report.

The methodology employed by the Department in the prevention and treatment of Hepatitis C is fully explained in Attachments 1 through 4. These attachments contain the Department's protocol for education and treatment for Hepatitis C and related documents and forms. Patient information material provided to all inmates at an orientation upon reception into the facilities, including the Baltimore City Detention Center, can be found at Attachment 1, Appendices 3 and 4. At the time of reception, inmates are also informed that if they believe that they are at risk for having contracted the Hepatitis virus, they are to

submit a sick call slip to further explore the issue with a Registered Nurse when they arrive at the institution. Once the inmate is educated on the risk and prevention issues and is sentenced, the treatment assessment process begins. As noted, the process is fully articulated in the attachments and can be seen in a process flow outline in Attachment 5.

Since the beginning of the new inmate health care contract in July 2005, the Department has provided educational handouts on the subject of Hepatitis C risk and prevention to over 150,000 arrestees at the Central Booking facility in Baltimore. Prior to the new contract, Hepatitis C information was not routinely provided to these individuals. Now every person entering the Central Booking Facility receives this educational handout. Any individual entering the Central Booking Facility, who is currently on Hepatitis C treatment, will continue treatment if they continue to be held in the detention center. Individuals receiving “medication continuation” services are not counted as a part of our Hepatitis C treatment population because this is a population that transitions relatively quickly and the numbers change daily.

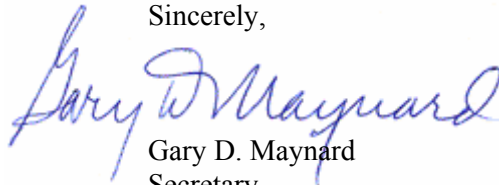
The contracts in place prior to the current contract did not provide for the treatment of Hepatitis C. Indeed it was as these contracts were in their last renewal period that the issue of treating individuals in correctional settings was gaining prominence in attention as a health issue. The Department had been exploring the issue for some years and in 2003 began to consider the treatment of individuals with Hepatitis C on a case-by-case basis. At the end of FY 2004, the Department committed to treat individuals who were co-infected with HIV and Hepatitis C. The difficult and time-consuming process of assessing eligible candidates and some reluctance to fully engage in this process on the part of some of the contractors so near to the end of the contract resulted in very few individuals actually entering treatment during that time. With the new contract, however, the Department’s intent to treat eligible individuals (including mono-infected individuals) was clearly articulated. As a result, since the start of the new contract, over 30,000 individuals entering the State prison system have received educational material and verbal instruction on the subject of Hepatitis C risk and prevention. Approximately 1,400 of those individual consented to and were found appropriate for testing. Of these individuals, 59 had initiated treatment, with 93% of those individuals initiating treatment in this fiscal year. With intake into the facilities anticipated to remain fairly stable in the out years, about 10% growth (see below) in the number of those individuals being tested, enrolled in Hepatitis Chronic Care Clinics, and being treated is expected over the next three years. The increase is anticipated to be a function of overcoming startup lag and increased interest among the population in being tested and receiving treatment, having seen other individuals go through the process and as a result of better public education related to the disease.

	FY 07	FY 08	FY 09	FY 10
Initiating Treatment	59	65	71	79
Receiving Education	15785	16000	16000	16000
Tested for Hep C	748	823	905	996
Enrolled in Chronic Care	1846	2031	2234	2457

The Department believes that the contract for health services provides for sufficient staff to continue to meet the demand, and the strategies and processes already in place appear to be functioning appropriately.

I hope this report and the attachments are sufficient to satisfy the JCR requirements and will facilitate the release of the \$100,000 of the Department's appropriation associated with the Office of the Secretary. If I or the Department can be of further assistance, please do not hesitate to contact me at 410-339-5005.

Sincerely,



Gary D. Maynard
Secretary

Enclosure

c: Senator Patrick J. Hogan, Vice Chair, Senate Budget and Taxation Committee
Senator James E. DeGrange, Sr., Chair, Senate Public Safety, Transportation, and Environment Subcommittee
Delegate James Proctor, Vice Chair, House Committee on Appropriations
Delegate Charles Barkley, Chair, House Subcommittee on Public Safety and Administration
Members of the House Committee on Appropriations
Members of the House Health & Government Operations Committee
Members of the Senate Budget and Taxation Committee
Members of the Senate Education, Health & Environmental Affairs Committee
Mr. Matthew Gallagher, Deputy Chief of Staff, Governor's Office
Mr. Joseph Bryce, Governor's Legislative and Policy Director
Mr. Sean Malone, Governor's Deputy Legislative Officer
Mr. Warren G. Deschenaux, Director, Department of Legislative Services
Ms. Rebecca Moore, Policy Analyst, Department of Legislative Services
Ms. Diane Lucas, Supervisor, Budget Analysis, Department of Budget and Management
Ms. Elizabeth H. Moss, Staff, House Committee on Appropriations
Mr. Edward M. Cheston, Staff, Senate Budget and Taxation Committee
Ms. Cathy Kramer, Department of Legislative Services
Ms. Sarah Albert, Department of Legislative Services
Deputy Secretary Mary L. Livers, DPSCS
Deputy Secretary G. Lawrence Franklin, DPSCS
Assistant Secretary Richard B. Rosenblatt, DPSCS
Assistant Secretary David Bezanson, DPSCS
Director Rhea L. Harris, Office of Legislative Affairs, DPSCS



**DEPARTMENT OF PUBLIC SAFETY
AND CORRECTIONAL SERVICES**

Report on Hepatitis C Prevention and Treatment

July 1, 2007

Martin J. O'Malley, Governor
Anthony G. Brown, Lt. Governor
Gary D. Maynard, Secretary

Pursuant to 2007 JCR Page 146
HB 50/Ch. 487, 2007

ATTACHMENTS

ATTACHMENT ONE

MANAGEMENT OF HEPATITIS C (HCV) INFECTION IN MARYLAND INMATES

Purpose: *To provide medical guidelines for providers and define standards of care for inmates diagnosed with Hepatitis C (HCV) infection.*

Scope: This protocol applies to the provision of medical services in all DPSCS facilities.

Definitions: The terms associated with the diagnosis, management, and treatment of the hepatitis C virus (HCV) have the following meanings:

Alpha interferon - Interferon is released by leukocytes in response to a viral infection. Several forms of alpha interferon are available for use as a therapeutic medication (alpha-2a, and consensus interferon).

Alanine aminotransferase (ALT) - An enzyme found primarily in the liver. It is released into the bloodstream as the result of liver damage. Also called serum glutamic pyruvic transaminase (SGPT). In chronic hepatitis C, increases in ALT range from 0 to 20 times (but usually less than five (5) times) the upper limit of normal.

Ascites - A buildup of fluid in the abdomen. Ascites is usually caused by severe liver disease such as cirrhosis.

Chronic hepatitis C virus infection - The presence of detectable hepatitis C virus in the bloodstream at least six months after acute infection.

Cirrhosis - A chronic liver condition caused by scar (fibrous) tissue and cell damage. Cirrhosis makes it hard for the liver to remove poisons (toxins) like alcohol and drugs from the blood. These toxins build up and may affect brain function.

Co-infection - Simultaneous infection of HIV and chronic hepatitis C.

Combination Therapy- The use of more than one medication at a time to combat a disease.

Computerized tomography (CT) - A radiologic technique that combines multiple x-ray images into a two (2) dimensional cross-section.

Conjunctivitis Sicca (Sjören's Syndrome) - A condition that may be related to HCV. Characterized by drying and inflammation of the conjunctiva (a clear membrane that coats the inner aspect of the eyelids and the outer surface of the eye) as a result of insufficient lacrimal secretion. When found in association with xerostomia (dry mouth) and arthritis of multiple joints, it is called Sjörgen's syndrome.

Cryoglobulinemia - The most common of hepatitis C complications that do not involve the liver. It is characterized by the presence in the blood of immune globulin complexes that precipitate below normal physiological temperatures. It is marked by: skin rashes, such as purpura, vasculitis, or urticaria; joint and muscle aches; kidney disease; neuropathy; cryoglobulins; and rheumatoid factor.

Decompensated liver disease – End stage liver disease.

Edema - A condition in which the body tissues contain an excessive amount of fluid. In liver cirrhosis, this is caused by obstructed blood flow through the liver due to scar tissue formation.

Eradication - Eradication of hepatitis C virus infection is characterized by undetectable HCV ribonucleic acid (RNA) in the bloodstream after a period of acute or chronic viremia.

Esophageal varicosities - Varicosities of the veins of the esophagus. These are associated with increased portal vein pressure, usually caused by cirrhosis of the liver.

ETOH - Ethanol alcohol. This is the alcohol found in beer, wine and liquor.

FDA - Food and Drug Administration. The government body responsible for assuring the testing and safety of new medications.

Fibrosis – The formation of scar tissue in the connective tissue framework of the liver following inflammation.

Gilbert's Syndrome - A hereditary disease due either to a deficiency of the enzyme glucuronyl transferase, excess bilirubin production, or a hemolytic disorder. The disease causes no symptoms, but an excess of unconjugated bilirubin is present in the urine.

Gynecomastia – The development of abnormally large breasts in the male.

HAART – The acronym for Highly Active Antiretroviral Therapy used in HIV to describe potent anti-HIV medication regimens.

HCV Antibody Test (ELISA) – The general term for a lab test that if positive represents exposure to the hepatitis C virus.

Hemochromatosis - A disease of iron metabolism in which iron accumulates in body tissues.

Hemoglobin - The iron-containing pigment of the red blood cells. Its function is to carry oxygen from the lungs to the tissues.

Hemoglobin (Hb) A1c - In diabetes mellitus, when the blood glucose level is optimally and carefully regulated over a long period, five to six weeks, the Hgb A1c level is normal. If the blood glucose level has not been controlled (and has been abnormally elevated) in the preceding five to six weeks, the Hgb A1c blood level is increased.

Hemolytic anemia - Anemia resulting from destruction (hemolysis) of red blood cells. It is acquired from the effects of toxic agents, or may run in families (congenital).

Hepatic encephalopathy - Impaired central nervous system function due to liver disease. caused by an accumulation of by-products normally processed by the liver.

Hepatitis - Inflammation of the liver. It may be caused by a variety of agents, including viral infections, bacterial invasion, and physical or chemical agents.

Hepatitis C virus (HCV) – a non-A, non-B RNA virus, a viral hepatitis, usually mild but often progressing to a chronic stage; the most prevalent type of post-transfusion hepatitis.

Hepatocellular carcinoma – Cancer of the liver.

Hepatoma - A tumor of the liver.

Hepatomegaly - Enlargement of the liver.

Histologic - Pertaining to the microscopic examination of a body tissue.

Household transmission - Transmission of an infection to members of the household by use of common implements such as a razor or toothbrush.

Human immunodeficiency virus (HIV) – human T-cell lymphotropic virus type III; a retrovirus that is the etiologic agent of acquired immunodeficiency syndrome (AIDS).

Hyperthyroidism - A condition caused by excessive secretion of the thyroid glands, which increases the basal metabolic rate.

Hypothyroidism - A condition due to deficiency of the thyroid secretion, resulting in a lowered basal metabolism.

Idiopathic Thrombocytopenia Purpura (ITP) - A spontaneous and abnormally low platelet count without any clear cause. This is not uncommon in HIV infection.

Interferon - Interferons are natural substances produced by cells in response to viral infection and are believed to represent the body's first line of defense against viruses.

Interferon monotherapy - Use of interferon alone for treating chronic HCV.

Jaundice - Condition characterized by yellowness of skin, whites of eyes, mucous membranes, and body fluids due to deposition of bile pigment resulting from excess bilirubin in the blood. It may be caused by obstruction of bile passageways, excess destruction of red blood cells (hemolysis), or disturbances in functioning of liver cells.

Lichen planus - A disease that may be related to HCV. A primary disorder of the skin resulting in violaceous, polygonal, or flat skin lesions that are often itchy. Seen commonly on the wrists, shins, lower back and genitals.

Magnetic Resonance Imaging (MRI) - A technique to image internal structures of the body, particularly the soft tissues, often superior to x-rays.

Medical hold – the process of flagging for custody the fact that medical has asked to be contacted prior to the movement of the individual to another facility or region. This provides for the continuity of care for specialty medical care, i.e., surgical procedures with follow up/clearance by the surgeon and/or comprehensive diagnostic workups for any specialty service. (The DPSCS Form 130-100iR, entitled the Medical/Mental Health Report for Inmate Assignments is utilized for the implementation of a Medical hold.)

Muscle wasting - Progressive muscular atrophy. A clinical finding of cirrhosis.

Necrosis - Dead tissue of cells in the body.

Neuropathy - A general term denoting functional disturbances and/or pathological changes in the peripheral nervous system. If the involvement is in one nerve it is called mononeuropathy; in several nerves, mononeuropathy multiplex; if diffuse and bilateral, polyneuropathy. An uncommon extrahepatic manifestation of HCV.

Pegylated interferon - A modified form of alpha interferon in which polyethylene glycol (PEG) is added. The result is a “long-acting” interferon that can be given once a week. Dosage is determined by body weight.

Polymerase Chain Reaction (PCR) Assay - A lab test to confirm the diagnosis of hepatitis C. Tests for hepatitis C virus (HCV) ribonucleic acid (RNA) using a sensitive polymerase chain reaction (PCR) assay. The presence of HCV RNA in serum indicates an active infection. Testing for HCV RNA is also helpful in patients in whom EIA tests for HCV antibodies are unreliable.

Ribavirin - An oral antiviral that is usually given twice a day in a dosage determined by body weight.

Serotyping - Discerning the genotype of a unicellular organism as defined by antisera against antigens expressed on the surface.

Spider angioma - A skin lesion of abnormally dilated blood vessels.

Sporadic transmission - Describes transmission of an infection whose source is unknown. This occurs in about 10 percent of acute hepatitis C cases and in 30 percent of chronic hepatitis C cases. These cases are also referred to as sporadic, or community-acquired, infections. These infections may have come from exposure to the virus from cuts, wounds, or medical injections or procedures.

Sustained Virologic Response (SVR) - characterized by undetectable HCV RNA at least six months after the last dose of treatment.

Teratogenic - The development of abnormal structures in an embryo resulting in a severely deformed fetus.

Thrombocytopenia - Abnormally low platelet count.

Thyroid Stimulating Hormone (TSH) - A hormone responsible for regulating the body's metabolic rate. It is measured prior to treatment using interferon, then at regular intervals throughout interferon treatment to monitor thyroid function. Interferon may affect thyroid function, causing over active or under active changes.

TIW - Abbreviation for three times a week. Seen in medication dosing instructions.

TLTBI – Treatment for latent tuberculosis infection.

Viral load - The number of viral particles in a sample of blood plasma. Several methods are available for measuring the titer or level of virus in serum, which is an indirect assessment of viral load.

Viremia - The presence of detectable amounts of virus in the bloodstream.

Wilson's Disease - A hereditary syndrome transmitted as an autosomal recessive trait in which a decrease of ceruloplasmin permits accumulation of copper in various organs (brain, liver, kidney and cornea) associated with increased intestinal absorption of copper. Syndrome is characterized by degenerative changes in the brain, cirrhosis of the liver, splenomegaly, tremor, muscular rigidity, involuntary movements, spastic movements, psychic disturbances, dysphagia and progressive weakness.

Policy: *Inmates who have been diagnosed with Hepatitis C virus (HCV) infection, shall undergo appropriate evaluation and treatment in accordance with current standards of medical practice. HCV infected inmates will be enrolled in chronic care clinics for education, medical evaluation, treatment and the monitoring of their disease status as outlined in this document.*

Procedure:

- A. The assessment and management of HCV shall be under the supervision of a physician experienced in the management of this disease.
- B. Co-infection HCV/HIV treatment is a priority as these patients are most likely to experience complications associated with the Hepatitis C virus.
- C. A thorough chart review shall be completed on every inmate's medical file prior to initiation of Step 1 to identify existing hepatitis related documentation, as well as to perform a review of the exclusionary criteria for antiviral treatment as outlined in Section F.
 1. Complete Appendix 1, HCV Evaluation Work Sheet for the documentation of the exclusionary criteria for antiviral treatment and hepatitis work-up.

D. **Diagnosis (Step 1):** With patient consent, HCV testing will be conducted where clinically indicated by the following risk factors, such as:

- Inmates with HIV infection or chronic HBV infection;
- Inmates with ALT levels persistently elevated for six (6) months (above two (2) times normal in tests taken at three (3) months intervals), or in three (3) of five (5) tests taken in one (1) year;
- As clinically indicated, e.g., inmates with signs or symptoms of acute or chronic hepatitis;
- Inmates with percutaneous exposures to blood;
- Inmates on chronic hemodialysis (screen ALT levels monthly and anti-HCV by immunoassay semiannually).

1. Pre-test counseling will occur so that inmates are provided with basic information regarding transmission, diagnosis and prevention measures for HCV. During the counseling session, an informed consent form (Appendix 2) will be presented to the inmate for signature to indicate his/her understanding and agreement to testing.
2. Hepatitis screening panel will be drawn and sent to the lab for analysis unless record review demonstrates previous/recent testing.
3. Post-test counseling will be conducted, and documented, for all inmates undergoing HCV testing and will consist of delivery of HCV basic education information, HCV lab results with basic interpretation of results and possible options for further treatment with review of exclusionary criteria for antiviral treatment.

E. **Management (Step 2):** If *the inmate* is found to be HCV antibody positive, then he/she will be enrolled in a Hepatitis Chronic Care clinic.

1. At first chronic care visit, the medical provider will verify the HCV antibody test and provide further education about the management of HCV disease. This will be documented on the HCV Informed Consent Sheet, (Appendix 2). *Inmates* who are mono-infected, non-complicated cases, may be scheduled for return visits outside of the routine chronic care appointments at the discretion of the physician. A note explaining the decision and when the next appointment is scheduled should be written in the progress note, and documented in the infectious disease database. At a minimum these patients should be seen annually.
2. The inmate will be given "Hepatitis C Virus: Fact Sheets/Education sheets," (Appendices 3 and 4). This will be documented on the HCV Informed Consent Sheet, (Appendix 2.)
3. Orasure screening for HIV status will be completed if the HIV status is unknown following the guidelines/protocol for Orasure testing.
4. Vaccination: *The inmate* will be given the first vaccinations for hepatitis A and B as appropriate. Consent for immunization must be obtained and filed in the medical record. The remainder hepatitis A and B

immunizations will be completed during the inmate's visit to the hepatitis chronic care clinic visits.

- a. Documentation of the administration of the vaccination shall be completed on the DPSCS immunization record.
- b. The DPSCS immunization record shall be maintained in the patient's medical record and filed behind the Problem List located in the front cover of the medical record.

5. Specific lab workup: *the inmate* will be provided with education about the remainder of the workup and the possibility for antiviral therapy. Consent will be obtained to continue the workup and the following will take place:

- a. Obtain the following lab tests:
 - i. Comprehensive chemistry to include at a minimum: albumin, bilirubin, CBC, creatinine, ALT, TSH, HIV test (with pre/post test counseling per AIDS Administration guidelines), PT-INR,
 - ii. If female, pregnancy test,
 - iii. If known diabetic, Hg A1c.
- b. Obtain ALT baseline results, monitor at three (3) and six (6) month intervals for sustained elevation of enzyme levels. If sustained, or continued, without **any exclusionary criteria**, proceed to "c" and "F."
- c. *If the inmate* agrees to further medical work-up, a HCV Viral Load will be drawn to determine chronic infection (vs. clearance of the virus). This will be documented on the HCV Recommended Labs Flow Sheet, (Appendix 5.)

F. Initial/General Eligibility Screening (Step 3): *If the inmate* is found to have HCV present on viral load analysis, then general screening for antiviral treatment will occur. Documentation of baseline HCV VL will be placed on the HCV Recommended Labs Flow Sheet, (Appendix 5.) **Write an order to place the inmate on Medical Hold on DPSCS Form 130-100iR.**

1. General Exclusionary Criteria: If the inmate has any of the following conditions, then he/she will not be eligible for antiviral therapy. He/she will be enrolled in chronic care clinic for monitoring. Documentation of all the following will be noted on Appendix 1.

- a. *Age <18, or age >60 years.*
- b. Life expectancy less than 10 years.
- c. Remaining incarceration time <24 months.
- d. History of solid organ transplant.
- e. Known/documented history of autoimmune disease.
- f. *Known/documented compliance rate with any chronic care conditions/visits, and/or medication adherence <80%. (eg. Poor HgA1C, TLTBI RX, etc.)*
- g. Known/documented alcohol and/or illicit drug use within previous 12 months. (Check OMSR)
- h. Pregnancy

- i. AIDS (CD4 <200, VL >50,000 copies)
- j. Decompensated liver disease
- k. Decompensated mental health condition
- l. **Active, or history of, an Axis I or Axis II Psychiatric**

Diagnosis:

- **Obtain a mental health consultation for documentation and confirmation of an active, or history of, an Axis I or Axis II diagnosis;**
- **Submit the Psychiatry Referral Form to the institutional psychiatrist for confirmation of an active, or history of, an Axis I or Axis II diagnosis. (Appendix 6.)**
- **Regional Medical Director/designee will be responsible for the submission of a copy of the completed psychiatry referral form to be included with the Hepatitis C Treatment Request packet to the DPSCS Medical Director's office. (see section "J" below.)**

G. Genotype Testing (Step 4) - If inmate **does not meet the above exclusionary** criteria, then he/she will undergo HCV genotype testing.

H. Treatment Plan (Step 5) - Upon receipt of the HCV genotype results, the medical provider will meet with *the inmate* and discuss/formulate HCV treatment plans according to current standard of care

1. If inmate's ALT levels have remained persistently elevated for six (6) months (above two (2) times normal in tests taken at three (3) months intervals, or in three (3) of five (5) tests taken in one (1) year in the Chronic Care Clinic), the patient shall be referred to a GI or ID specialist, unless further testing or **treatment is already absolutely contraindicated per exclusionary criteria** above. The consult should request an opinion from the specialist regarding:

- a. Liver biopsy
- b. Inmates' candidacy for antiviral HCV therapy.

2. The inmate shall already be placed on a "medical hold."

3. Obtain liver biopsy to assess degree of fibrosis and inflammation, unless there is a contraindication that was missed initially.

4. Refer back for follow-up to GI/ID specialist with copies of the documentation of completed hepatitis C workup, including histology report for pathology of liver biopsy.

5. If liver biopsy is normal or shows minimal fibrosis - monitor/re-biopsy in five (5) years.

6. If liver biopsy shows portal or bridging fibrosis and moderate inflammation and necrosis - consider antiviral therapy in Chronic Care Clinic.

7. If liver biopsy shows decompensated hepatic disease, the inmate will not be a candidate for antiviral therapy, follow up patient in Chronic Care Clinic.
 8. If the inmate refuses the liver biopsy, there will be no further need to proceed with antiviral therapy consideration, continue to see the inmate in the Chronic Care Clinic. Document refusal for biopsy *in both the medical record as well as in the Infectious Disease database.*
- I. Submit Hepatitis C Treatment Request to *Regional Medical Director/designee* and the DPSCS Hepatitis C Clinical Review Panel for Review (Step 6) - All pertinent documentation should accompany the treatment request in order that an informed decision may be made. Documentation should include, but is not limited to, completed appendices one (1), two (2), five (5) and six (6).
 - J. Submit Hepatitis C Treatment Request to DPSCS Medical Director's office for review - a complete copy of all supporting documentation, including all supporting blood work, liver biopsies, mental health consultation, and signed consent forms shall be faxed to the DPSCS Medical Director's office. The submission form accompanying the above documents shall be signed and dated by the referring *Regional Medical Director/designee*.
 - K. Receipt of Hepatitis C Treatment Request by DPSCS Medical Director: Upon receipt of the treatment request, the DPSCS Medical Director's office shall do the following:
 1. Review the submitted documentation for completeness.
 2. Utilize the DPSCS Clinical Review Panel for review of the GI opinion and Histology report.
 3. Communicate one of the following determinations from the review of the DPSCS Hepatitis C Clinical Panel to the referring *Regional Medical Director/designee*.
 - i. Pending: more information needed,
 - ii. Approved: initiate treatment on site following recommendations of specialist consultant,
 - iii. Referred: to GI or ID Specialist for concerns/further evaluation/treatment,
 - iv. ***Denied: secondary to inappropriateness for antiviral treatment, continue to monitor in Chronic Care Clinic.***
 - L. If *the* determination is made to initiate antiviral drug therapy, the following process shall occur:
 1. HIV/Hepatitis C Virus documentation shall be placed on patient's chart.
 2. Hepatitis C Virus Recommended Labs flow sheet (Appendix 5) will be placed on patient's chart.

3. If HCV genotype 2 or 3:
 - a. Treat with pegylated interferon/ribavirin combination therapy for 24 weeks; and
 - c. Recheck HCV viral load (HCV RNA, quantitative) at completion of treatment.

4. If HCV genotype 1:
 - a. Treat with pegylated interferon/ribavirin therapy and;
 - b. Recheck HCV viral load (HCV RNA, quantitative) at 12 weeks.
 - i. If viral load has not decreased by two (2) logs (10^2) at 12 weeks-discontinue therapy. Patient must sign waiver for discontinuation of therapy.
 - ii. If viral load has decreased by two (2) logs (10^2) at 12 weeks, continue therapy for 48 weeks. Recheck HCV viral load (HCV RNA, quantitative) at completion of treatment.
 - iii. ***(Submit copy of above documentation to the DPSCS Medical Director and Hepatitis C Clinical Review Panel Also, document in both medical record and Infectious Disease database.)***

5. For all genotypes, if ribavirin is contraindicated treat with pegylated interferon for the duration of the treatment regimen.

6. Monitor post-treatment
 - a. Repeat ALT every two (2) months for six (6) months after completion of effective therapy.
 - b. Measure HCV viral load (HCV RNA, quantitative) six (6) months after completion of effective therapy.
 - c. Referral to drug education/treatment program if appropriate and available and not previously completed.

M. Notification of Inter-Regional Transfers of Patients on HCV Antiviral Therapy – the sending Regional Medical Director/designee shall immediately notify the receiving Regional Medical Director/designee of any inter-regional transfers of patients on HCV Antiviral Therapy, and shall provide patients status report of same. Additionally, the sending Regional Medical Director/designee shall notify the DPSCS Medical Director of this transfer.

The sending Regional Infection Control Coordinators shall notify immediately the receiving Infection Control Coordinator of any inter-regional transfers of patients on HCV Antiviral Therapy and shall provide patients status report of same. Additionally, the sending Regional Infection Control Coordinator/designee shall notify the DPSCS Infection Control Director/designee of this transfer.

N. Reporting - Infection Control Coordinators will submit monthly status reports to the DPSCS Infection Control Director that provide the following information (which should also be documented in the infectious disease database):

- The number of inmates per facility who are known to be infected with HCV and also the number of co-infected HCV/HIV;
- The number of inmates who received liver biopsy;
- The number of inmates per facility receiving interferon/ribavirin therapy;
- The number of inmates per facility receiving pegylated interferon alone, due to contraindication for ribavirin therapy;
- The number of inmates per facility completing each week of the above procedure during the month:
 - a. The number of inmates who have completed Week 1 – Week 48.
 - b. The number of inmates who have completed therapy.
 - c. The number of inmates who have discontinued antiviral therapy with reason.

References:

- A. Correctional Medical Services, Chronic Hepatitis C Pathway, Clinical Pathway T-070.54, Version 4.2, April 21, 2004.
- B. Federal Bureau of Prisons, Clinical Practice Guidelines for the Prevention and Treatment of Viral Hepatitis, February, 2003.
- C. Sulkowski MS, Thomas DL. Hepatitis C in the HIV-infected person. *Ann Intern Med* 2003; 138:197-207.

Appendices:

Appendix 1 - HCV Evaluation Work Sheet, May, 2005

Appendix 2 - HCV Informed Consent Sheet, May, 2005

Appendix 3 - Hepatitis C & HIV Co-infection Fact Sheet, May, 2005

Appendix 4 - Just the Facts: Hepatitis C in Maryland Prisons, May, 2005

Appendix 5 - Maryland DPSCS Hepatitis C Virus Recommended Labs Flow Sheet

October, 2004; Updated: May, 2005

ATTACHMENT ONE

APPENDIX 1

Appendix 1
HCV Evaluation Work Sheet

Patient Name		DPSCS NO:		Facility
(LAST)	(First)	(MI)	SID NO:	
REVIEW/DOCUMENTATION OF EXCLUSIONARY CRITERIA				
YES	NO			
<input type="checkbox"/>	<input type="checkbox"/>	Age <18, or age >60	Age: _____	
<input type="checkbox"/>	<input type="checkbox"/>	Life expectancy less than 10 years		
<input type="checkbox"/>	<input type="checkbox"/>	Remaining incarceration time <24 months	Rel. Date: _____	
<input type="checkbox"/>	<input type="checkbox"/>	History of solid organ transplant		
<input type="checkbox"/>	<input type="checkbox"/>	Known/documented history of autoimmune disease		
<input type="checkbox"/>	<input type="checkbox"/>	Adherence to any chronic care visits and/or medication adherence <80%	____% Compliance (eg. Poor Hg A1c, TLTBI RX, etc)	
<input type="checkbox"/>	<input type="checkbox"/>	Known/documented alcohol and/or illicit drug use within previous 12 months. (OMSR Verified)	Date: _____	
<input type="checkbox"/>	<input type="checkbox"/>	Pregnancy		
<input type="checkbox"/>	<input type="checkbox"/>	AIDS CD4 <200; VL >50,000 copies		
<input type="checkbox"/>	<input type="checkbox"/>	Decompensated liver disease		
<input type="checkbox"/>	<input type="checkbox"/>	Decompensated Mental Health Condition		
<input type="checkbox"/>	<input type="checkbox"/>	Mental Health DX (or H/O DX): _____	Axis I	<input type="checkbox"/> Axis II <input type="checkbox"/>
HCV Pre-Test Counseling Conducted	DATE: _____	By: _____		
HCV Informed Consent Signed/Declined	DATE: _____	By: _____		
HCV Antibody Drawn	DATE: _____	By: _____		
HCV Post-Test Counseling Conducted	DATE: _____	By: _____		
Enrolled in Chronic Care Clinic	DATE: _____	By: _____		
HCV Patient Education Provided	DATE: _____	By: _____		
HCV Pt. Info Sheet Given	DATE: _____	By: _____		
<i>If HIV status unknown:</i>				
Date of HIV Test	DATE: _____	Results	_____	
Vaccinations:				
Hepatitis A	DATE: _____	By: _____		
	DATE: _____	By: _____		
Hepatitis B	DATE: _____	By: _____		
	DATE: _____	By: _____		
	DATE: _____	By: _____		
Twinrix	DATE: _____	By: _____		
	DATE: _____	By: _____		
	DATE: _____	By: _____		
ID/GI consult	DATE: _____	By: _____		
HCV Viral Load Drawn	DATE: _____	By: _____		
General Screening Performed	DATE: _____	By: _____		
HCV Genotype testing	DATE: _____	TYPE: _____		
Risk Strat/TX Options Reviewed with Pt.	DATE: _____	By: _____		
DPSCS PANEL REVIEW FOR LIVER BIOPSY		Date Reviewed:	Comments	
Liver Biopsy Recommendation	YES	NO	DPSCS concurs	
By ID/GI consult	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signature _____
Referral to Site Medical Director/Site ID staff for Review		Date Reviewed:	Signature _____	
Referral to Regional Medical Director for Review		Not Appropriate for Therapy <input type="checkbox"/>	Recommend Therapy <input type="checkbox"/>	
Date Reviewed:	Signature: _____			
Submission of Case to DPSCS Panel:	Date: _____	By: _____		
Received at DPSCS/HQ	Date: _____	By: _____		
Notification of Pt Transfer to Region:	Date: _____	By: _____		

DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES

DPSCS HEPATITIS C CLINICAL PANEL REVIEW

Patient Name	DPSCS NO:	Facility
(Last) (First) (MI)	SID NO:	

DPSCS Hepatitis C Clinical Panel Determination:

- Pending: More information needed (see below)
- Approved: Proceed with appropriate interferon/ribavirin protocol
- Referred: to GI or ID Specialist for futher evaluation
- Denied: Not Appropriate for Antiviral RX continue to monitor in CCC
- Copy of liver Biopsy and Histology

Recommendations/Reasons:

DPSCS Medical Director Signature:	Date:
DPSCS Infectious Disease Consultant Signature:	Date:

ATTACHMENT ONE

APPENDIX 2

HCV INFORMED CONSENT SHEET

I have been informed that I am infected with the Hepatitis C virus and due to this I am formally requesting treatment to be initiated by the medical staff in the medical unit. The physician has fully advised me regarding the Hepatitis C Virus natural history, its effects on my health, and the steps I can take in order to decrease the impact of the disease on my health. I understand that treatment with medications works in only some people, and that staying away from alcohol and drugs that are not prescribed by a doctor are equally important to helping me, whether or not I take the medications to get rid of the virus.

Furthermore, I have been advised by the physician that treatment, which most often involves two medications, one injected and the other by mouth may not be effective in treating my Hepatitis C virus infection. These medications might even make my liver worse, and they would have to be stopped. The overall chance of successful treatment is roughly equal to the chance of unsuccessful treatment.

I understand that there are numerous and potentially life threatening side effects that may occur during and after medication therapy. Birth defects are a special problem: severe and potentially life threatening birth defects could result if a female becomes pregnant, or if I am male and either make a female pregnant or have sex with a pregnant woman. This danger persists for up to six months following the last dose of medication for hepatitis. By signing this form, I pledge to use two forms of contraception (for example both a condom and birth control pills) when having sex for six months following my last dose of medication.

Side effects may include a “flu” like illness including muscle aches and loss of appetite; many potential mental problems, like depression, irritability, uncontrollable anger, and other problems. The medication can also cause gastrointestinal upset or bleeding, heart problems, kidney problems, lung problems, and anemia (low blood counts). The medication also can cause an increased potential to get other infections, and there have been cases where infection is deadly. Sleep disturbances and hair loss are also common side effects. Numerous other side effects of the medication may occur and will be monitored with routine laboratory studies and clinic visits. In the event a side effect of the medication does occur, then treatment will be altered accordingly.

I understand that after **12 weeks** of therapy, I will be evaluated for response for the therapy. At that time a decision will be made as to the whether continued therapy is appropriate for my condition, or if the health care team should focus on interventions without the medications. I further understand that compliance with the therapy regimen (**taking the medication as ordered**) is vital to the success of the therapy.

Noncompliance with therapy regimen can result in the stopping of the medication therapy.

Regardless of the treatment outcome, I am fully aware that maintaining my overall health offers the best opportunity to long term survival with Hepatitis C virus. By signing this document, I acknowledge that I have read the above information, and that it has explained to me by a health care provider. Further, I have had an opportunity to ask questions about my proposed evaluation and potential treatment.

Patient's Signature	Date Signed:
Provider's Signature	Date Signed:

INITIATION OF CHRONIC CARE CLINIC INTERVENTION/PATIENT EDUCATION (FORM HCV3, APPENDIX) PROVIDED TO PATIENT

Patient's Signature	Date Signed
Provider's Signature	Date Signed:

I consent to medication treatment to include an interferon product and Ribavirin. I understand that I may withdraw or cancel this consent in writing at anytime.

Patient's Signature	Date Signed:
Provider's Signature	Date Signed:

Appendix 2

ATTACHMENT ONE

APPENDIX 3

Why are people infected with HIV also at risk of being infected with HCV?

HCV (hepatitis C virus) and HIV (human immunodeficiency virus) share similar modes of transmission/exposure from contaminated blood or other body fluids. This means that the same risky behavior that put them at risk of contracting HIV places them at risk for HCV. These risk factors include: exposure to contaminated needles through use of injectable drugs, body piercing, tattooing, acupuncture, practicing high-risk sexual behaviors, and receiving blood transfusions or solid organ transplants prior to 1992 when blood screening for HCV became routine.



Is the problem of HIV-HCV co-infection well known?

Unfortunately, the prevalence of HCV co-infection in the HIV-infected population is not well recognized. HIV specialty physicians and primary care physicians are now becoming increasingly aware of the co-infection problem. As a result, screening for HCV infection in HIV positive patients is now becoming more routine. This is an encouraging development.

Is early diagnosis of HCV infection important?

Yes, early diagnosis is important in the treatment of HCV infection. HCV can cause liver damage even before there are any symptoms. The earlier the diagnosis, the earlier education regarding “Harm reduction” and support monitoring/treatment can be discussed.

Does HIV affect the progression of HCV?

Data suggest that HIV makes HCV progress more rapidly, which in turn causes liver damage more quickly. That’s why it’s particularly important for early diagnosis and treatment of HCV infection in the HIV population.

Do the medications to treat HIV and HCV infection work together?

The treatment of HIV and HCV co-infection can be complicated. The primary medication used to treat HCV infection is interferon, which can compromise the body’s immune function – this can be problematic for HIV infected persons whose immune system is already weakened by HIV. In addition, the side effects of antiretroviral therapy for HIV infection can be more troublesome when combined with the side effects associated with HCV infection treatment. For example, zidovudine (Retrovir®) used to treat HIV, and ribavirin (Retelto®) used to treat HCV, can both cause anemia. Because the treatment of HIV and HCV co-infections can be complicated, the best partners to guide you through this maze of medication management are doctors and pharmacists who have training and experience in serving both specialized populations.

How will the medication needs of the co-infected HIV/HCV population be addressed?

Again, it is important to have specialized, expert professionals on your side. Your doctor may refer you to consultants to help with this. There are numerous considerations, including dosage adjustments and therapy modification, monitoring of liver function and disease progression, managing side effects and helping you stay on track with taking your medications on time. They will need your help.

Are HIV medications harmful to the liver?

Many HIV medications are broken down by the liver and can cause injury to the liver. This can be particularly problematic in the case of HCV co-infected patients whose livers are already

compromised. Again, medication management must be guided by a trained health care professional.



Why should I get vaccinations for Hepatitis if offered?

It would prevent your liver from getting worse from other types of hepatitis and possibly prevent liver failure.

ATTACHMENT ONE

APPENDIX 4

Just the Facts:HEPATITIS C IN Maryland PRISONS

FACT: Hepatitis C (HCV) is a slowly progressive infection that affects a small percentage of those persons infected. Even then liver inflammation can take as long as 15-20 years to cause problems.

FACT: Treatment is not started as soon as the diagnosis is made.

The problems take years to develop and there is adequate time to observe patients to determine if treatment is needed.

FACT: HCV is carried in the blood and can be spread by coming into contact with blood from someone who has the virus. High risk behavior includes, using other people's needles, razors, toothbrushes, etc., increases the risk of getting Hepatitis C, as does unprotected sex, body piercing, tattoos and injecting drugs and barbers who do not disinfect the clippers.

FACT: Many people do not realize they have contracted the disease because symptoms usually go away and often do not reappear for many years. Symptoms can occur between two weeks and six months after exposure.

FACT: Symptoms are similar to the flu and can induce muscle aches, headaches, nausea, fever, vomiting, fatigue, and weakness. Common complaints!

FACT: Based on a DPSCS March, 2003 Study, it is estimated that 7,314 or about 31% of state inmates in Maryland have tested positive for the HCV virus. 1000 inmates are HIV infected and at least 496 inmates are co-infected with HIV/HCV.

FACT: The people *most at risk* for problems with HCV are co-infected with HIV infection. DOC has made treatment for the co-infected a priority.

FACT: Most people have genotype 1 of Hepatitis C that is less than 50% affected by medications for Hepatitis C treatment. The treatment is for 48 weeks for this genotype. Genotype 2 is treated for 24 weeks and is usually more responsive to medications.

FACT: Even after Hepatitis C treatment is successful, the virus may return or you can be infected with a different hepatitis virus if risk behavior is not stopped.

FACT: Because Hepatitis A infection can cause severe liver disease in patients who have HIV disease; vaccination against hepatitis A & B will be made available for inmates co-infected with HCV/HIV.

FACT: A liver biopsy is how the extent of damage from the hepatitis virus will be determined along with lab studies for liver enzymes.

FACT: Interferon and ribavirin are two drugs that are used to treat Hepatitis C. One is given as a "Shot" 3 times a week. The other is taken by mouth twice daily.

FACT: Some inmates who have the virus while in prison will not be treated. Not all people with HCV will benefit from treatment and many people are excluded from treatment because of other medical considerations such as, tuberculosis, immune deficiency diseases, cancer, cirrhosis, prior organ transplant, age restrictions, or blood disorders. People with histories of some psychiatric disorders such as depression, psychosis, and bipolar disorder, and/or suicide gestures may not benefit from treatment.

FACT: Some inmates will not tolerate the drug therapy for this disease. Some inmates do not want to be treated and some are too close to their release date to begin treatment with adequate follow-up as most treatment is for 48 weeks, and 6 months follow-up post treatment is required. It is generally considered more damaging to begin treatment for HCV and not finish it than it is to not receive treatment at all.

FACT: Residents of the pretrial facilities will not be candidates for treatment for Hepatitis C since the stay is too short to complete treatment. Detainees on therapy for Hepatitis C when arrested may be considered candidates for continuation of therapy, on a case-by-case basis, if the arrest is not substance abuse related and they have been compliant on medications.

FACT: Any person testing HCV positive, Only(mono-infected) will be enrolled in a chronic care clinic to receive HCV education, mental health assistance, additional lab studies, including testing for HIV and consideration for antiviral therapy. Inmates for whom antiviral treatment is not appropriate will be encouraged to continue their enrollment in the chronic care clinic.

FACT: Because Hepatitis C is affecting millions of people both inside and outside of prison, it is important to learn the facts about HCV. For more information check out the following websites: www.cdc.gov (Center for Disease Control and Prevention), www.liverfoundation.org (American Liver Foundation.)

Brochures about HCV are available to inmates from the medical and mental health staff.

Office of Inmate Health Service

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October, 2004

ATTACHMENT ONE

APPENDIX 5

Appendix 5(a)

Patient Name:										DOC Number:				
Week	CBC (PLT)	PT-INR	Complete Chemistry	LYTES	BUN	CR	GLUCOSE	ALT/AST	URIC ACID	BILIRUBIN	ALBUMIN	HCV RNA QUANT	b-HCG	DATE
21														
22														
23														
24														
25														
26														
27														
28														
29														
30														
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44														
45														
46														
47														
48														

CBC, PT/INR/Chem (lytes, BUN, Creat, gluc, ALT, AST, and uric acid to be done at weeks: 1,2,4,8,12,16,20,24,28,32,36,40, and 44.

Bili-Alb and TSH to be done at weeks 12,16,20,24,28,32,36,40, and 44. HCV/RNA quant to be done at weeks 12 and 48 for Genotypes 1 and 4; 0 and 24 weeks for Genotypes 2 and 3.

ALT only to be done at week 48. **BHCG** (females) to be done monthly.

Appendiz 5(b)

ATTACHMENT TWO

Psychiatry Referral Form

Patient's Name:	DOC Number:	Site:
Birth date:	Age:	Sex:

PURPOSE:

Screening evaluation for Hepatitis C Management – Please provide documentation of inmate's active or history of an Axis I or Axis II diagnosis.

Psychiatric History:

1. Major Depression
2. Schizophrenia
3. Suicidal history
4. Other:
5. Other:

Past Medical History:

1. HIV
2. HCV
3. Other:
4. Other:

Medications:

YES – Stable, on psychiatric Medications 6 months or more

NO - Stable, on psychiatric Medications 6 months or more

YES – Active or history of an Axis I or Axis II diagnosis.

NO - Active or History of an Axis I or Axis II diagnosis.

Physician's Signature:

ATTACHMENT THREE



Department of Public Safety and Correctional Services

Office of Inmate Health Care Services

6776 REISTERSTOWN ROAD • SUITE 315 • BALTIMORE, MARYLAND 21215-2342
(410) 585-3377 • FAX (410) 764-5112 • TOLL FREE (877) 379-8636 • V/TTY (800) 735-2258 • www.dpscs.state.md.us

Management of Hepatitis C Infection in Maryland Inmates Biopsy Request Process 7-17-06

Inmates, who have been diagnosed with Hepatitis C virus infection, shall undergo appropriate evaluation and treatment in accordance with the current standards of medical practice and DPSCS protocol. HCV infected inmates who meet the criteria without any contraindications per the exclusionary criteria may follow the following steps to request the liver biopsy.

1. Complete the HEP C Protocol work up:
(No exclusionary criteria noted)
 - Copy of psych evaluation – attached to request
 - Copy of HCV antibody results
 - Copy of HCV viral load
 - Copy of HCV genotype
 - Copy of HIV status
 - Co-morbidities → chronic diseases: Diabetes, Hepatitis B, Dialysis, etc are documented
 - Copy of Alpha Fetal Protein (AFP) results
 - Copy of ANA results
 - Copy of Ferritin results
 - Copy of CBC, INR/PT, Elevated LFT's (report must show elevated 2x normal in 3 out of 5 tests taken in 1 year)
2. **Request** the GI/ID consult for evaluation for liver biopsy to Wexford during collegial review with all of the above documentation referenced in Section 1 (above) for ID/GI consultation. Fax *all* of the data listed above to Wexford for the collegial review.
3. Consultation by Dr. Rufael or any outside ID/GI consultant for Liver Biopsy do the following:
Complete Formal DPSCS consult request post approval by Wexford and attach the same information for the ID/GI consultant section 1 (Hold on to this data as DPSCS will require this information and the **completed** consultation request for panel review)
4. **Post Specialty Consultation completion**
 - Make copies of completed Specialty consultation form with specialist recommendations regarding liver biopsy.
 - Submit all materials to the DPSCS Hep C nurse along with Section 1. data including **the completed specialty consultation information**
5. **Request for Liver Biopsy at the DPSCS Panel via Teleconference**
 - DPSCS Panel discussion during teleconference: DPSCS Panel has reviewed the information and **concurs** that a liver biopsy is needed and

the case should be presented to Wexford for authorization, post review of all of the data including the consultants completed report.

- Proceed with securing Authorization from Wexford for liver biopsy
- Fax copy of completed GI/ID consultation to Wexford, along with DPSCS panel agreement with liver biopsy recommendations.

6. Wexford role for reviewing a liver biopsy request for hepatitis treatment

- All data from sections 1, DPSCS panel disposition and completed ID/GI consultation Post specialty consultation recommending liver biopsy should be faxed or e-mailed to Dr. Smith/Pat Casey for liver biopsy authorization
- Date of DPSCS panel presentation by provider and copy of disposition of DPSCS Panel should be available for review by Wexford UM Director
- Wexford will acknowledge that there has been a DPSCS panel disposition and authorize liver biopsy procedure and place in their system
- Wexford to proceed with routine processes for their approved procedures.

Post Biopsy - Histology reports post liver biopsy

All liver biopsy pathology results need to be faxed to OIHS-DPSCS Hepatitis Panel as soon as the results are obtained irrespective of the candidates' status regarding anti viral therapy. A copy of the pathology report should be available to Wexford upon request.

ATTACHMENT FOUR

APPENDIX 1

HEPATITIS C
PRE-TESTING COUNSELING

Hepatitis C is a disease of the liver caused by the hepatitis C virus (HCV). It is found in the blood of persons who have this disease. The infection is spread by contact with the blood of an infected person.

You may be at risk for Hepatitis C if you :

- Have ever injected illegal drugs, even if you experimented a few times many years ago.
- Have history of HIV infection.
- Have history of Hepatitis A or B.
- Had frequent contact with blood in the work place, especially accidental needlesticks.
- Have signs and symptoms of acute or chronic hepatitis.
- Ever had sex with a person infected with Hepatitis C.
- Lived with someone who was infected with HCV and shared items such as razors or toothbrushes that might have had blood on them.
- Were notified that you received blood from a donor who later tested positive for hepatitis C.
- Have received a blood transfusion or solid organ transplant before July, 1992.
- Were treated for clotting problems with blood product made before 1987.
- Have ever been on long-term kidney dialysis.
- Have evidence of liver disease (e.g., persistently abnormal ALT levels).

You should be tested for HCV because it is important to catch it early so you can :

- Be checked for liver disease.
- Get treatment, if indicated. Drugs are licensed for the treatment of persons with long-term hepatitis C.
- Learn how you can protect your liver from further harm.
- Learn how you can prevent spreading HCV to others.

What blood tests are available to check for hepatitis C.

Several blood tests can be done to determine if you have been infected with HCV. Your doctor may order just one or a combination of these tests. A single negative test does not prove that a person is not infected. Virus may be present in the blood and just not found. Also, a person infected in the past who has recovered may have a negative test. Therefore, your doctor may repeat your test if it is negative.

You can also have a false positive test. A false positive test means that the test looks as if it is positive, but it is really negative. This is the reason why you may be asked to have another test done..

I hereby acknowledge that I have read and understand this information. I further acknowledge that I was given adequate time to ask questions and that my questions were answered to my satisfaction.

Inmate Print Name: _____ **DOC#** _____

Inmate's Signature: _____ **Date:** _____

Signature of Healthcare Provider _____ **Date:** _____

Appendix 1

ATTACHMENT FOUR

APPENDIX 2

Hepatitis C
Post-test Counseling

You were recently tested to determine if you have been infected with Hepatitis C. Your doctor will discuss the test results with you and will inform you of his recommendations.

If your test results indicate that you are not infected with Hepatitis C, here are some facts you need to know about:

TRANSMISSION OF HEPATITIS C

- Hepatitis C Virus (HCV) is spread through sharing needles or “works” when “shooting” drugs, through needlesticks or sharps exposures on the job, or from an infected mother to her baby during birth.

- HCV occurs when blood from an infected person enters the body of a person who is not infected.

PREVENTION

- There is no vaccine to prevent hepatitis C.
- Do not shoot drugs; if you shoot drugs, stop and ask your doctor about a treatment program; if you can’t stop, never share needles syringes, water, or “works”.
- Do not share personal care items that might have blood on them (razors, toothbrushes).
- If you are exposed to sharps and needles while working, always follow routine precautions and safely handle needles and sharps.
- Consider the risks if you are thinking about getting a tattoo or body piercing. You might get infected if the tools have someone else’s blood on them or if good health practices are not properly followed.
- HCV can be spread by sex, but this is rare. People who are having sex with more than one steady sex partner should use latex condoms correctly and every time to prevent the spread of sexually transmitted diseases.

I hereby acknowledge that I have read and understand this information. I further acknowledge that I was given adequate time to ask questions and that my questions were answered to my satisfaction.

Inmate Print Name: _____ **DOC#** _____

Inmate’s Signature: _____ **Date:** _____

Signature of Healthcare Provider _____ **Date:** _____

ATTACHMENT FOUR

APPENDIX 3

Hepatitis C
Post-test Counseling for HCV infected inmates

You were recently tested to determine if you have been infected with Hepatitis C. Your doctor will discuss the test results with you and will inform you of his recommendations.

- **Facts on People with HCV**

The Hepatitis C virus (HCV) is a liver disease caused by infection with the hepatitis C virus (HCV). HCV is spread by contact with the blood of an infected person, and can cause liver inflammation and scarring. Disease progression can result in increasing inflammation and scarring. Eighty-five percent of individuals exposed to HCV develop chronic hepatitis C; only about 15% clear the virus spontaneously within a few months of infection. Once HCV becomes chronic it remains in the body unless successfully treated. Not everyone with HCV progresses to being sick. 20% of individuals chronically infected with HCV alone developed scarring and inflammation of the liver and this usually takes as long as 10-30 years to develop.

- **Facts on People with both HCV and HIV (co-infection).**

It has been suggested that having HIV may impair clearance of HCV. When a person has HIV and HCV, it's referred to as co-infection. Hepatitis C progression appears to be more rapid in HIV-infected individuals compared to persons with HCV alone. Several studies have found that progression could be as much as 2-5 times faster.

- **Symptoms of Hepatitis C**

A person infected with HCV may experience flu-like symptoms such as malaise, fatigue and weakness. But, often there are no symptoms. With chronic infection, HCV usually progresses slowly for years and there are few symptoms, until serious liver damage occurs.

- **Diagnosis and Testing**

The Key tests are: ALT, genotype, HCV viral load, and biopsy.

1. **ALT:** ALT is a substance that your liver releases when it is under pressure, sick or dying.
2. **Genotype:** the HCV genotype test can predict your response to treatment and dictates the type and length of treatment.
3. **HCV viral load:** this test can detect the presence of virus in your blood and can measure the viral load.
4. **Biopsy:** If you are co-infected with both HIV and HCV, please request that you speak with your doctor about having a liver biopsy. The biopsy may not always be necessary, but it is usually very important in deciding when to begin therapy, what type of treatment a person will receive, and in evaluating how much and what kind of damage has been done to the liver.

- **Treatment for HCV and the Co-Infected Person**

A person who is HCV-infected should ask his or her doctor the following question: when do I begin HIV and/or HCV therapy and what are my options for treatment? Each person's situation is different, and treatment decisions should consider the individual's situation, the outcome of treatment, and the disease stages of their HIV and HCV.

There is actually one treatment for HCV: *Interferon* and *Ribavirin*. This therapy can be difficult to tolerate. Side effects can include: fatigue, irritability, depression, anemia, weight loss, flu like symptoms, among others. **However, a person infected with HCV has a better chance to respond to therapy if he/she takes the prescribed medications REGULARLY. Each individual is different and treatment decisions should be determined on an individual basis.**

I hereby acknowledge that I have read and understand this information. I further acknowledge that I was given adequate time to ask questions and that my questions were answered to my satisfaction.

Inmate Print Name: _____ **DOC#** _____ **Signature** _____ **Date** _____
Health Care Provider print name: _____ **Signature:** _____ **Date** _____

ATTACHMENT FIVE

