SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA 2006–0094]

RIN 0960–AF28

Revised Medical Criteria for Evaluating Digestive Disorders

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving digestive disorders. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, methods of evaluating digestive disorders, treatment, and our program experience. We are also removing listings that are redundant because they only refer to other listings, and we are making other conforming changes.

DATES: These rules are effective December 18, 2007.

FOR FURTHER INFORMATION CONTACT: James Julian, Director, Office of Medical Policy, Social Security Administration, 4470 Annex Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, 410–965–4015. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet Web site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html.*

Background

We are revising and making final the rules we proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on November 14, 2001 (66 FR 57009). We provide a summary of the provisions of the final rules below, with an explanation of the changes we have made from the text in the NPRM. We also provide summaries of the public comments and our reasons for adopting or not adopting the recommendations in these comments in the section, ''Public Comments.'' The final rule language follows the public comments.

After we published the NPRM, we also:

- Published final rules on April 24, 2002, entitled Technical Revisions to Medical Criteria for Determinations of Disability (67 FR 20018). In those final rules, we added listings 5.09 and 105.09 for liver transplantation. We also made minor technical changes to our listings to include references to modern imaging techniques. These final rules do not make substantive changes to the rules we published on April 24, 2002, although we are making minor editorial changes.
- Published a notice on November 8, 2004, providing a 60-day extension of the comment period on the NPRM for the limited purpose of accepting comments about the proposals regarding chronic liver disease (69 FR 64702). We explain this extension in more detail in the public comments section of this preamble.
- Held an outreach meeting in Cambridge, Massachusetts on November 17, 2004, regarding our listings for chronic liver disease. We describe this meeting in more detail in the public comments section of this preamble.

Why are we revising the listings for digestive disorders?

We reviewed the prior digestive disorder listings and determined that they should be revised in light of our program experience and advances in medical knowledge, methods of evaluating digestive disorders, and treatment. We last published final rules comprehensively revising the digestive disorder listings in the **Federal Register** on December 6, 1985 (50 FR 50068). In the introductory text to those rules, we stated our intention to periodically review and update these listings due to medical advances in treatment and our program experience.

What do we mean by ''final rules'' and ''prior rules''?

Even though these rules will not go into effect until 60 days after publication of this notice, for clarity we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

When will we start to use these final rules?

We will start to use these final rules on their effective date. We will continue to use our prior rules until the effective date of these final rules. When these final rules become effective, we will apply them to new applications filed on or after the effective date of these rules and to claims pending before us, as we describe below.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date when we make a determination or decision, including those claims in which we make a determination or decision after a remand to us from a Federal court. With respect to claims in which we have made a final decision and that are pending judicial review in Federal court, we expect that the court would review the Commissioner's final decision in accordance with the rules in effect at the time the final decision of the Commissioner was issued. If a court reverses the Commissioner's final decision and remands the case for further administrative proceedings after the effective date of these final rules, we will apply the provisions of these final rules to the entire period at issue in the claim in our new decision issued pursuant to the court's remand.

How long will these rules be in effect?

These rules will be in effect for 5 years after the date they become effective, unless we extend them or revise and issue them again.

What general changes are we making that affect both the adult and childhood listings for digestive disorders?

We are clarifying the listing criteria and making them easier to use by:

- Removing reference listings and, when appropriate, providing guidance in the introductory text of the listings. Reference listings are listings that are met by satisfying the criteria of another listing. For example, an impairment could meet prior listing 5.03, Stricture, stenosis, or obstruction of the esophagus, with weight loss ''as described under listing 5.08.'' Prior listing 5.08 required weight loss of a specific amount due to ''any persisting gastrointestinal disorder.'' Therefore, prior listing 5.03 was redundant because we could also evaluate weight loss from stricture, stenosis, or obstruction of the esophagus under listing 5.08 alone.
- Removing or updating outdated listings.
- Adding criteria to the listing for chronic liver diseases and expanding the guidance in the introductory text on how we evaluate these diseases, including specific guidance on chronic viral hepatitis infections.
- Revising and adding criteria to the listing for inflammatory bowel diseases and expanding the introductory text to include guidance on how we evaluate these digestive disorders.
- Adding a listing for short bowel syndrome and providing guidance in the introductory text for this disorder.

• Expanding the introductory text to include guidance on how we consider the effects of treatment.

• Providing general guidance in the introductory text explaining how we evaluate digestive disorders that do not meet these listings.

• Making nonsubstantive editorial changes to update the medical terminology in the listings and to be consistent with plain language guidelines.

We discuss other changes in the listings below, in our detailed explanation of the revised listings.

How are we changing the introductory text to the listings for evaluating digestive disorders in adults?

5.00 Digestive System

We are revising the introductory text for this body system to provide additional guidance for evaluating digestive disorders and to update its medical terminology. We are also removing references to digestive disorders and complications of digestive disorders, such as peptic ulcer disease, fistulae, and abscesses, that generally are not of listing-level severity. (However, as we explain below, we are including fistulae and abscesses as criteria in final listing 5.06 for inflammatory bowel disease.)

We are including relevant material from prior 5.00A in final 5.00A and final 5.00C.

We are updating and moving relevant material from prior 5.00B to final 5.00G.

We are moving relevant material from prior 5.00C to final 5.00E. We are removing the portion of prior 5.00C that dealt with peptic ulcer disease because advances in diagnosis, evaluation, and treatment of this impairment make the surgical interventions discussed in the prior section (including gastrectomy, vagotomy, and pyloroplasty) much less common.

Following is a detailed, section-by-section explanation of the final introductory text material.

5.00A—What kinds of disorders do we consider in the digestive system?

This section revises prior 5.00A. We list the major types of digestive disorders included in these listings and provide an example of a complication that may result from them. In the NPRM, we proposed to include information in this section from prior 5.00C about colostomy and ileostomy. However, we moved this information to final 5.00E as part of the general reorganization of the introductory text. We also proposed to explain that gastrointestinal impairments frequently respond to treatment; therefore, their severity should be evaluated in the context of prescribed treatment. We moved this information to 5.00C, ''How do we consider the effects of treatment?'' where it more logically fits.

5.00B—What documentation do we need?

In this new section, we include examples of the types of clinical and laboratory findings that should be part of the longitudinal evidence. This section also includes two sentences describing appropriate medically acceptable imaging that were not in the NPRM, but that we added in the aforementioned final rules making technical, but not policy, changes to our listings. We revised the sentence describing medically acceptable imaging so that it more appropriately reflects imaging techniques used for digestive disorders. We also moved to this section a revised version of the first sentence of proposed 5.00C2, which explains that the specific findings required by these listings must occur within the period we are considering in connection with an individual's application or continuing disability review.

In response to public comments we describe later in this preamble, we removed the sentence in proposed 5.00B1 explaining that we usually need longitudinal evidence covering a period of at least 6 months of observations and treatment unless we can make a fully favorable determination or decision without it. Instead, we are providing timeframes for the evidence requirements in each listing.

We moved proposed 5.00B2, which explained how we evaluate claims when an individual has not received ongoing treatment or does not have an ongoing relationship with the medical community despite the existence of a severe impairment, to final 5.00C where it fits more logically with our discussion of treatment issues.

5.00C—How do we consider the effects of treatment?

In the NPRM, proposed 5.00C was titled, ''How do we evaluate digestive disorders that require recurring or persistent findings?'' Proposed 5.00C1 defined ''recurring'' and ''persisting'' as used in listings 5.02, 5.05, 5.06, and 5.08, and proposed 5.00C2 explained when the ''events'' required to satisfy the listings must occur. In these final rules, we removed the references to recurring or persistent findings from the digestive listings. We also moved the first sentence of 5.00C2 to final 5.00B. We no longer need the second sentence of proposed 5.00C2 because of changes we made to the listings. Therefore, we removed all of proposed 5.00C. We explain the reasons for the changes to the listings later in this preamble.

We explain how we consider the effects of treatment in final 5.00C. This section is an expansion of proposed 5.00D. It includes six paragraphs that address treatment issues, rather than the three paragraphs we proposed. As we have already noted, we moved the additional paragraphs from other sections to present the information more logically.

General Information About Final 5.00D Through 5.00G

In the NPRM, proposed 5.00F was titled ''What are our guidelines for evaluating specific digestive impairments?'' Proposed 5.00F1 addressed malnutrition and weight loss, and proposed 5.00F2 addressed chronic liver disease. In these final rules, we are greatly expanding the introductory text from the NPRM in response to public comments and adding more discussion about digestive disorders, especially chronic liver disease and inflammatory bowel disease. Since we are including significantly more information in these final rules, we are addressing each kind of digestive disorder in its own separate section. Also, the guidance about specific disorders under proposed 5.00F was not in the order of the proposed listings. In the final rules, we are providing guidance that generally follows the structure of the final listings. Thus:

• Final 5.00D addresses chronic liver disease (final listing 5.05);

• Final 5.00E addresses inflammatory bowel disease (final listing 5.06);

• Final 5.00F addresses short bowel syndrome (final listing 5.07); and

• Final 5.00G addresses weight loss due to any digestive disorder (final listing 5.08).

5.00D—How do we evaluate chronic liver disease?

In final 5.00D (proposed 5.00F2), we define chronic liver disease, provide examples of it, and describe its manifestations. In response to hundreds of public comments regarding hepatitis C, we are greatly expanding this section to explain how we evaluate chronic viral hepatitis, including chronic hepatitis B and C infections, and we describe extrahepatic manifestations of these infections. In addition, we include guidance for considering the effects of specific treatment modalities for hepatitis B and C infections. We also present information on conditions that we include in the chronic liver disease listing (that is, gastrointestinal

hemorrhage, ascites or hydrothorax, spontaneous bacterial peritonitis, hepatorenal syndrome, hepatopulmonary syndrome, hepatic encephalopathy, end stage liver disease, and liver transplantation).

Final 5.00D contains 12 sections:

• Final 5.00D1, D2, and D3 are a reorganization of the information presented in proposed 5.00F2(a), F2(b), and F2(d).

• In final 5.00D1, we define chronic liver disease and name the manifestations of chronic liver disease that we consider under these listings. We removed the phrase in proposed 5.00F2 indicating that chronic liver disease must be ''expected to continue for 12 months'' because it is unnecessary. Under our general rules for evaluating disability, an impairment must meet the duration requirement.

• We also removed the phrase in proposed 5.00F2d explaining that we would ''assess impairment due to hepatic encephalopathy under the criteria for the appropriate mental disorder or neurological listing(s).'' In response to public comments, we are adding a listing for hepatic encephalopathy (final listing 5.05F).

• Final 5.00D2 presents an expanded list of examples of chronic liver disease, including some diseases, such as Wilson's disease and chronic hepatitis, which we included in the heading of prior listing 5.05 but not in the heading of final listing 5.05.

• Final 5.00D3 is an expansion of proposed 5.00F2d. It has three paragraphs that describe the symptoms (5.00D3a), signs (5.00D3b), and laboratory findings (5.00D3c) associated with the manifestations of chronic liver disease.

In response to a comment, we are including guidance in final 5.00D3a to explain that symptoms may correlate poorly with the severity of chronic liver disease.

In final 5.00D3c, we are clarifying our intent in proposed 5.00F2d, where we explained that abnormal liver function test findings may correlate poorly with the clinical severity of liver disease. Although that guidance is applicable to liver function tests such as serum total bilirubin or liver enzyme levels, it is not applicable to all tests indicative of liver function. In final 5.00D3c, we now explain that abnormally low serum albumin or elevated International Normalized Ratio (INR) levels are exceptions because they are indicators of significant liver disease. As we note below, we include criteria for abnormally low serum albumin and elevated INR in final listings 5.05B and 5.05F.

We are also not including the statement from proposed 5.00F2d that liver function tests ''must not be relied upon in isolation'' because it is unnecessary. In final 5.00D3c, we are also expanding the rules from what we had proposed to include information on documenting chronic liver disease with a liver biopsy or imaging studies.

• Final 5.00D4 is new; there was no corresponding section in the NPRM. We added it in response to hundreds of comments concerning the growing incidence of hepatitis. In final 5.00D4a, we provide general information about chronic viral hepatitis infections. In final 5.00D4b, we provide information about chronic hepatitis B infection. In final 5.00D4c, we provide detailed information about chronic hepatitis C infection, including a paragraph explaining adverse effects of treatment that may contribute to a finding of disability. In final 5.00D4d, we provide information about the extrahepatic manifestations of hepatitis B and C infections that may result in, or contribute to, a finding of disability.

• Final 5.00D5 corresponds to proposed 5.00F2c. In it, we provide guidance for evaluating gastrointestinal hemorrhages under final listings 5.02 and 5.05A. As we explain in more detail below, we have revised proposed listings 5.02 and 5.05A in these final rules, and final 5.00D reflects the changes to the listings. For example, in response to comments, we expanded the scope of listing 5.05A to include hemorrhages from gastric or ectopic varices and portal hypertensive gastropathy in addition to hemorrhages from esophageal varices. Also in response to comments, we removed the proposed criterion for ''massive'' hemorrhage requiring transfusion of at least 5 units of blood in 48 hours. Instead, final listing 5.05A requires hemorrhaging which results in ''hemodynamic instability,'' which we describe in final 5.00D5.

• In final 5.00D6, we provide guidance for evaluating ascites or hydrothorax under final listing 5.05B. In response to comments, we have revised proposed listing 5.05B; therefore, final 5.00D6 reflects the changes we made to that listing. We explain those changes later in this preamble.

We also removed the statement in proposed 5.00F2d that current imaging techniques are capable of identifying even minimal amounts of ascites before they can be detected on physical examination. We made this change because final listing 5.05B is met based on laboratory findings coupled with documentation of the ascites or hydrothorax. If these laboratory findings are at the level specified in the listing, it is not necessary to quantify the ascites.

• Final 5.00D7, D8, and D9 are also new in these final rules. In response to comments, we are including listing criteria in final listing 5.05 for three serious complications of chronic liver disease: Spontaneous bacterial peritonitis (final listing 5.05C); hepatorenal syndrome (final listing 5.05D); and hepatopulmonary syndrome (final listing 5.05E). Each new section explains how the condition is diagnosed and the documentation requirements for the new listings.

• In final 5.00D10, we provide guidance for evaluating hepatic encephalopathy under final listing 5.05F. As noted earlier, we added this listing in response to comments. In 5.00D10a, we explain how hepatic encephalopathy is diagnosed and identify the documentation requirements for the new listing. In final 5.00D10b, we explain that we will not evaluate acute encephalopathy under listing 5.05F if it results from conditions other than chronic liver disease.

• Final 5.00D11 is also new in these final rules. In response to public comments, we added listing 5.05G, for end stage liver disease (ESLD) with SSA Chronic Liver Disease (SSA CLD) scores of 22 or greater. The SSA CLD calculation is a calculation we developed based on the Model for End Stage Liver Disease (MELD) calculation. The MELD is a numerical scale developed for the United Network for Organ Sharing (UNOS) that is used for liver allocation within the Organ Procurement and Transplantation Network. The MELD score is based on objective and verifiable medical data, and estimates an individual's risk of dying while waiting for a liver transplant. In final 5.00D11a, we explain that we will use the SSA CLD score to evaluate your end stage liver disease under final listing 5.05G. In final 5.00D11b–g, we explain how we calculate the SSA CLD score; for example, what laboratory values we use, when they must be obtained, and the formula we use to do the calculation.

• Final 5.00D12 corresponds to 5.00F2e and F2g in the NPRM. It explains how we evaluate liver transplantation 1 year after the date of the transplantation. The final rule is similar to the proposed rule; we edited it for clarity and expanded it slightly to provide more information about when liver transplantations are performed.

5.00E—How do we evaluate inflammatory bowel disease (IBD)?

In response to public comments, we are greatly expanding the listing criteria for inflammatory bowel disease, final listing 5.06, and adding a new section, final 5.00E, to the introductory text to provide guidance for evaluating IBD under these expanded criteria.

Final 5.00E contains four paragraphs:

- In final 5.00E1, we explain the general characteristics of IBD;
- In final 5.00E2, we list common symptoms, signs, and laboratory findings associated with IBD;
- In final 5.00E3, we describe some of the more common extraintestinal manifestations of IBD affecting different body systems; and
- In final 5.00E4, we explain how we consider surgical procedures such as ileostomy and colostomy. Final 5.00E4 corresponds to the first sentence of prior 5.00C and proposed 5.00A3.

5.00F—How do we evaluate short bowel syndrome (SBS)?

In response to public comments, we are adding a new listing for short bowel syndrome, final listing 5.07, and a new section in the introductory text, final 5.00F, to provide guidance for evaluating SBS under this listing.

5.00G—How do we evaluate weight loss due to any digestive disorder?

Final 5.00G corresponds to prior 5.00B and proposed 5.00F1 and reflects changes we made to proposed listing 5.08, discussed below. We are simplifying the guidance from prior 5.00B about evaluating malnutrition and weight loss. Under the final rules, it is sufficient for our purposes that the weight loss result from any medically determinable digestive disorder. We are also revising the heading of final 5.00G to refer only to weight loss, instead of the proposed reference to malnutrition and weight loss, to better reflect the content of the section.

We revised proposed listing 5.08 to use Body Mass Index (BMI) to evaluate weight loss instead of using height and weight measurements by gender. BMI is the measurement recommended by the Centers for Disease Control and Prevention (CDC) to determine appropriate weight for height. In final 5.00G1, we explain that we use BMI to evaluate weight loss due to any digestive disorder under listing 5.08 and to evaluate lesser weight loss from IBD under listing 5.06B. The latter is one of the new criteria that we added to the IBD listing in response to public comments.

In final 5.00G2, we explain how we calculate BMI. The change from height and weight measurements to BMI removed the need to provide rules for rounding of height and weight measurements; therefore, we do not include in these final rules the rules for rounding that were in proposed 5.00F1a–F1c.

5.00H—What do we mean by the phrase ''consider under a disability for 1 year''?

Final 5.00H corresponds to proposed 5.00F2f; however, we revised it to make clear that the phrase refers to the date on which we must determine whether an impairment continues to meet a listing or is otherwise disabling, not the date on which disability began. We explain that we do not restrict our finding about the onset date of disability to the date of a specific qualifying event in a listing, such as a liver transplant. For example, many individuals who need liver transplants (final listing 5.09) have impairments that meet one of the criteria for chronic liver disease (final listing 5.05) before they have their liver transplants.

In the proposed rules, we had inadvertently included the explanation of the phrase ''consider under a disability for 1 year'' under the heading for chronic liver disease; however, we also use the phrase in final listing 5.02 for gastrointestinal hemorrhaging from any cause. Therefore, in the final rules, we explain the phrase in a section that is independent of the discussion of chronic liver disease, and we identify the three listings to which it applies.

In proposed 5.00F2f, we had also stated that the phrase was a ''statement about the expected duration of disability.'' In reviewing that language, we realized that it could have been misunderstood to mean that we presume that an individual will no longer be disabled after 1 year. That was not our intent. Rather, we intended to indicate only that after 1 year the impairment would no longer meet the requirements of the particular listing that includes the criterion. The impairment may still be disabling at the end of the period because it may meet or medically equal another listing or result in a residual functional capacity that is consistent with a finding of disability. Also, when we consider whether an impairment continues to be disabling, we apply the medical improvement review standard in §§ 404.1594 and 416.994. For these reasons, we are not including the statement in these final rules.

5.00I—How do we evaluate impairments that do not meet one of the digestive disorder listings?

Final 5.00I is generally the same as proposed 5.00E, except that we include hepatitis B or C that results in depression as an example of a digestive impairment we would evaluate in another body system, instead of the hepatic encephalopathy example we included in proposed 5.00E1. This example was no longer appropriate because we have a listing for hepatic encephalopathy (5.05F) in the final rules.

How are we changing the listings for evaluating digestive disorders in adults?

5.01 Category of Impairments, Digestive System

Removal of Redundant or Reference Listings

We are removing four prior listings because they were reference listings and, therefore, were redundant. These four listings were met by referring to the requirements of prior listing 5.08:

- 5.03—Stricture, stenosis, or obstruction of the esophagus with weight loss;
- 5.04D—Peptic ulcer disease with weight loss;
- 5.06E—Chronic ulcerative or granulomatous colitis with weight loss; and
- 5.07D—Regional enteritis with weight loss.

All of these impairments are still covered by final listing 5.08. Chronic ulcerative or granulomatous colitis and regional enteritis are also covered by final listing 5.06. We no longer mention them explicitly in these final rules because they have been replaced by the more encompassing term ''inflammatory bowel disease.''

Prior listing 5.05E, hepatic encephalopathy, was also a reference listing, referring to listing 12.02. In the NPRM, we proposed to remove the listing and to add language in proposed sections 5.00E1 and 5.00F2b that reminded adjudicators to evaluate the impairment under the criteria for the appropriate mental disorder or neurological listing. However, in response to many public comments, we decided to remove the proposed guidance and to provide a new listing specifically for hepatic encephalopathy in the digestive listings, final listing 5.05F. Therefore, while we are still removing prior reference listing 5.05E, we are including a different listing for hepatic encephalopathy in these final rules.

We are also removing the following prior listings because medical knowledge, methods of evaluating digestive disorders, advances in treatment, and our program experience indicate that they are no longer appropriate indicators of listing-level severity. There has been significant progress in the treatment of these digestive disorders. Many of these disorders can be controlled or resolved and thus are less likely to be of listing-level severity. Even if listing-level severity is initially present, the 12-month statutory duration requirement will often not be met.

- 5.04—Peptic ulcer disease (demonstrated by endoscopy or other appropriate medically acceptable imaging). Advances in medical and surgical management have made less common many complications from peptic ulcer disease, such as recurrent ulceration (prior listing 5.04A), fistula formation (prior listing 5.04B), and recurrent obstruction (prior listing 5.04C). Treatment often results in significant improvement, therefore the prior listing criteria for these impairments are no longer appropriate indicators of listing-level severity.
- 5.05B—Chronic liver disease with performance of a shunt operation for esophageal varices. When we first published this listing, only surgical shunts involving extensive abdominal surgery were available. These surgeries were not usually performed until the chronic liver disease became serious enough to justify the risks associated with prolonged surgery and anesthesia. More recently, transjugular intrahepatic portosystemic shunts (TIPS), which are performed with minimal anesthesia and with fewer complications, have largely replaced abdominal surgical shunts in treating the complications of portal hypertension, such as bleeding gastroesophageal varices or refractory ascites. However, in the final listing for hepatic encephalopathy, final listing 5.05F, we are adding a criterion for a history of TIPS in combination with other findings that describe an impairment that is of listing-level severity.
- 5.05C—Chronic liver disease with specific levels of serum total bilirubin. Prior listing 5.05C required only a persistently elevated serum total bilirubin level. We are removing this listing because this laboratory finding alone does not correlate sufficiently with the ability to function.
- 5.05F—Chronic liver disease with liver biopsy. This listing required confirmation of chronic liver disease by a liver biopsy, with another specified clinical or laboratory finding. We are removing this listing because a liver biopsy, while confirming the presence of liver disease, does not correlate with any specific level of impairment severity or decrease in ability to function. We assess the clinical findings described in prior listings 5.05F1 and F3 in other final listings, and we are removing the requirement for elevated serum total bilirubin level in prior listing 5.05F2 because it does not sufficiently demonstrate impairment severity or correlate with the ability to function.
- 5.06A—Chronic ulcerative or granulomatous colitis with recurrent bloody stools documented on repeated examinations and anemia manifested by hematocrit of 30 percent or less. These criteria alone were not appropriate indicators of listing-level severity. However, we have incorporated a criterion for anemia in final listing 5.06, the new listing for IBD that we added in response to public comments.
- 5.06B and 5.07—Persistent or recurrent systemic manifestations, such as arthritis, iritis, fever, or liver dysfunction due to chronic ulcerative or granulomatous colitis or regional enteritis. These listings required only the presence of a systemic manifestation in another body system or organ, without regard to degree of severity or impact on functioning. Therefore, they were not appropriate indicators of listing-level severity. However, in response to public comments described below, we are including examples of significant extraintestinal manifestations in final 5.00E3 with instructions to our adjudicators to consider these manifestations when determining whether the individual has an impairment(s) that meets or medically equals another listing and when assessing residual functional capacity. The examples include arthritis, iritis, and other effects.
- 5.06C and 5.07C—Intermittent obstruction due to intractable abscess, fistula formation, or stenosis as a result of chronic ulcerative or granulomatous colitis or regional enteritis. Advances in surgical treatment have improved the management of these disorders, thus these listings are no longer appropriate indicators of listing-level severity. However, in final listing 5.06B, we include intestinal obstruction, abscess, fistula, and stenosis as criteria that can satisfy the requirements of the listing.
- 5.06D—Recurrence of findings in listing 5.06A, B, or C after total colectomy. We are removing this listing consistent with our removal of listings 5.06A, B, and C.
- 5.08B—Weight loss due to any persisting digestive disorder, with weight equal to or less than the values specified in Table III or IV and one of the listed abnormal laboratory findings present on repeated examinations. This listing allowed a lesser level of weight loss than that required to meet listing 5.08A when accompanied by one of the additional listed findings. Those findings, however, did not correlate with any specific level of impairment severity or decrease of ability to function that would be an accurate indicator of listing-level severity. However, in response to public comments, we are including a 10 percent weight loss from baseline as one of the criteria that can be used to meet final listing 5.06 for individuals who have IBD.

The following is a detailed explanation of the final listings.

Listing 5.02—Gastrointestinal Hemorrhaging From Any Cause, Requiring Blood Transfusion

We are expanding this listing to include ''gastrointestinal hemorrhage from any cause'' instead of the prior listing's ''upper gastrointestinal hemorrhage from undetermined cause.'' We are also revising the severity criterion in this listing from anemia with a persistent hematocrit level of 30 percent or less, to a requirement for gastrointestinal hemorrhages that require blood transfusions of at least 2 units of blood per transfusion, occurring at least three times, at least 30 days apart, during a consecutive 6-month period. A hematocrit level by itself is generally not an appropriate indicator of the severity of gastrointestinal hemorrhage, and as we have already noted, does not necessarily correlate with inability to function.

In these final rules, we are clarifying the proposed rule to explain that an individual does not have to be hospitalized for transfusions under this listing. We did not indicate whether hospitalization was required in the proposed rule. Therefore, this is only an editorial change for clarity.

The proposed listing indicated in a parenthetical statement that ''[a]ll incidents [hemorrhages] within a consecutive 14-day period constitute one episode.'' In the final listing, we are revising this statement by removing references to ''incidents'' and ''episodes'' and instead simply using the word ''transfusions,'' since transfusions are the indicators of severity. Also, in response to a public comment, we are increasing the length of time between blood transfusions (described as ''episodes'' in the proposed rule) from 14 days to 30 days.

Since improvements in medical treatment may resolve the frequency of hemorrhages and thus the overall severity of the impairment, we indicate that we will consider an individual to be under a disability for 1 year following the last documented transfusion. After that, we will evaluate the residual impairment(s).

Listing 5.05—Chronic Liver Disease

We are replacing prior listing 5.05 with criteria that more accurately reflect listing-level severity.

• We are removing the parenthetical examples of chronic liver diseases from the heading of prior listing 5.05 because these references could have been misinterpreted to mean that we included only those specific conditions under the listing. However, in response to comments, we continue to use Wilson's disease and chronic hepatitis as examples of chronic liver diseases that are covered by final listing 5.05 in final 5.00D2 of the introductory text. In a change from the NPRM, and in response to many comments, we are revising the heading of the listing to refer to ''chronic liver disease'' only. We removed ''and cirrhosis of any kind'' from the heading because cirrhosis is a form of chronic liver disease.

• In final listing 5.05A, we are expanding the scope of prior and proposed listing 5.05A in response to comments to include hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy. The proposed listing required ''massive'' hemorrhage requiring ''5 units of blood in 48 hours.'' In response to comments, we changed the requirement for ''massive'' hemorrhage to hemorrhaging that results in hemodynamic instability, and we changed the transfusion requirements from the proposed ''5 units of blood in 48 hours'' to ''at least 2 units of blood.'' We chose 2 units of blood because this is the minimum amount of blood that is usually transfused. We define ''hemodynamic instability'' in 5.00D5.

Newer techniques in primary prevention and treatment of bleeding gastroesophageal varices, for example, TIPS, banding, sclerotherapy, and laser therapy, have significantly improved the management of bleeding varices. Based on these advances, it is no longer appropriate to presume disability for 3 years as under prior listing 5.05A. Therefore, the final listing (like the proposed listing) provides that we will consider an individual disabled for 1 year following the last documented transfusion. After that, we will evaluate the residual impairment(s).

Final listing 5.05B corresponds to prior listing 5.05D, ascites due to chronic liver disease. In response to comments, we are also including hydrothorax in the listing because ascitic fluid can collect in the chest cavity and result in a very serious impairment. Therefore, we are including thoracentesis in the documentation requirements in final listing 5.05B1 because it provides a definitive diagnosis of hydrothorax, just as paracentesis provides a definitive diagnosis of ascites.

As in the NPRM, we are revising the required time period in which the evaluations showing ascites or hydrothorax must occur from 5 months to 6 months because, in our experience, a 6-month period enables us to make a more reliable prediction of duration of an impairment of listing-level severity. We also are requiring that evaluations be done at least 60 days apart within the 6-month period to substantiate the chronic nature of the impairment.

In response to public comments, final listing 5.05B2 now requires documentation of ascites or hydrothorax by physical examination or by appropriate medically acceptable imaging, but not both, as we proposed in the NPRM. However, if the ascites or hydrothorax is documented by physical examination or imaging rather than paracentesis or thoracentesis, we require additional laboratory findings that confirm very serious chronic liver disease. As in proposed listing 5.05B2a, we require serum albumin of 3.0 g/dL or less. In response to public comments, we changed the proposed criterion for a measure of prothrombin time to a criterion for an elevated International Normalized Ratio (INR) of at least 1.5 in final listing 5.05B2b. The public comments correctly indicated that INR is a more widely used study.

• In response to public comments, we are also adding three new listings for serious complications of chronic liver disease: Final listing 5.05C for spontaneous bacterial peritonitis; final listing 5.05D for hepatorenal syndrome; and final listing 5.05E for hepatopulmonary syndrome. These complications are so severe that we require only one occurrence of any one of them, shown by the requisite findings, to satisfy the listing.

• As already noted, we are also adding a new listing 5.05F for hepatic encephalopathy. The new listing requires hepatic encephalopathy documented by abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness, present on at least two evaluations at least 60 days apart within a consecutive 6-month period, with associated physical signs or laboratory findings, occurring with the same frequency and during the same time period; or a history of a TIPS or any surgical portosystemic shunt procedure.

• In response to comments that individuals on liver transplant lists should qualify, we are adding another new listing, final listing 5.05G, for evaluating individuals with ESLD. We are using an SSA CLD score criterion as an objective means to measure listing-level severity. As discussed above, we based the SSA CLD calculation on the MELD calculation used by UNOS to prioritize individuals ages 12 and over on a national liver transplantation list according to the severity of their liver disease. (There is also a Pediatric End Stage Liver Disease scoring system, called PELD, for children under age 12. We have developed an SSA Chronic Liver Disease—Pediatric (SSA CLD–P) calculation based on that system that we have included in the part B listings, as we explain below.) The SSA CLD score determination relies only on objective criteria, with standardized laboratory determinations that are readily available and reproducible.

We did not agree that all individuals on transplant lists should qualify under our listings because the threshold criteria for placement on a transplant list vary widely throughout the country and some individuals are placed on transplantation lists well before they have listing-level impairments. In the final rule, we provide that a SSA CLD score of 22 or greater meets the listing. We chose this score based on the clinical severity represented by the laboratory values contained in the SSA CLD score.

For final listing 5.05G, we require two calculations of SSA CLD scores, at least 60 days apart, and that the scores must be calculated within a consecutive 6-month period, consistent with other provisions in these final rules.

Listing 5.06—Inflammatory Bowel Disease

We are combining portions of prior listings 5.06 and 5.07 into final listing 5.06. Ulcerative colitis, Crohn's disease, granulomatous colitis, and regional enteritis are now commonly referred to as ''inflammatory bowel disease'' (IBD).

In the NPRM, proposed listing 5.06 required documentation of IBD with persistent or recurrent intestinal obstruction. The proposed listing repeated the criteria from prior listing 5.07A, clarified that the intestinal obstruction must be documented by appropriate medically acceptable imaging or operative findings, and

included the requirement for documentation of two episodes of obstruction over a consecutive 6-month period despite prescribed treatment, to ensure that there is a chronic impairment.

In response to public comments, we are significantly revising and expanding final listing 5.06. As in the proposed listing, the introductory paragraph of final listing 5.06 requires documentation of IBD by endoscopy, biopsy, appropriate medically acceptable imaging, or operative findings. As in the NPRM, final listing 5.06A requires obstruction of stenotic areas in the small intestine or colon with proximal dilatation. We are clarifying in the final rule that adhesions do not satisfy the requirement for obstruction. This is not a substantive change but a clearer statement of our intent that there must be obstruction that results from IBD. We are also clarifying that, in these cases, the stenotic areas may be shown by surgery or by medically acceptable imaging. In addition, we are clarifying the language we had proposed by requiring hospitalization for treatment of the obstruction (intestinal decompression or surgery). This is not a substantive change from the NPRM because listing-level obstruction of a stenotic area would require hospitalization for one of these types of treatment. Therefore, the requirement in the final listing will only help to confirm the existence of listing-level obstruction caused by IBD.

We are deleting the proposed requirement for persistent or recurrent obstruction over a consecutive 6-month period despite prescribed treatment in response to a public comment. Instead, we are requiring that the findings occur on at least two distinct occasions at least 60 days apart within a consecutive 6-month period.

Final listing 5.06B includes six other manifestations of IBD that were suggested by commenters. Consistent with most of the other criteria in the final rules for impairments that have episodic manifestations, final listing 5.06B requires that two of the six criteria be present on at least two evaluations, occurring at least 60 days apart within the same consecutive 6-month period, except for listing 5.06B6, which requires supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter.

Listing 5.07—Short Bowel Syndrome

As we explained earlier, we are removing prior listing 5.07, for regional enteritis. Instead, we evaluate this condition under final listing 5.06, for IBD. However, in response to comments regarding individuals who need parenteral nutrition, we are adding a new listing, final listing 5.07, for short bowel syndrome to address situations in which post-operative nutritional needs cannot be met orally or with supplemental enteral nutrition. This final listing requires a diagnosis of short bowel syndrome due to surgical resection of more than one-half of the small intestine with resulting dependence on daily parenteral nutrition via a central venous catheter.

Listing 5.08—Weight Loss Due to Any Digestive Disorder

In this final rule, we changed the heading of prior and proposed listing 5.08, ''Weight loss due to any persisting gastrointestinal disorder'' to ''Weight loss due to any digestive disorder.'' We deleted the word ''persisting'' for reasons we explain in the public comments section of this preamble.

In final listing 5.08, we are establishing the severity of the weight loss based on the CDC's BMI formula, rather than the Metropolitan Life Insurance Company's weight charts we used in the proposed rules and which were last updated in 1983. When we published the NPRM in 2001, we indicated that neither the CDC nor any other recognized authority known to us had determined a BMI for adults that would be consistent with listing-level severity weight loss. However, since that time, we determined that we could establish a BMI comparable to the severity standard in the weight charts. We established this BMI level in the final listing by calculating the BMI for each value on proposed weight tables I and II and averaging them.

We are changing to the more widely used BMI for several other reasons. For example, this change eliminates the need for gender tables, as BMI is not gender-specific in adults. Also, we were not able to apply the prior and proposed weight tables to individuals whose height was outside the table values, and instead had to review the evidence and determine whether the impairment medically equaled the listing. Now we can apply the BMI formula to all cases regardless of the individual's height. Also, our use of BMI in this body system is consistent with our use of BMI in Social Security Ruling 02–1p, Title II and XVI: Evaluation of Obesity (67 FR 57859).

Listing 5.09—Liver Transplantation

In the NPRM, we proposed to add listing 5.09 for liver transplantation. However, we published final rules adding this listing on April 24, 2002 (67 FR 20018) based on another NPRM in which we had also proposed to add this listing. (See 65 FR 6934.) Therefore, in these final rules, we are retaining the listing we published in April 2002, revising it to include the phrase ''1 year following the date of transplantation,'' and changing the punctuation to make it easier to read. The only public comments we received about this listing agreed that we should add it.

How are we changing the introductory text to the listings for evaluating digestive disorders in children?

105.00 Digestive System

As in the adult rules, we are revising the introductory text to the digestive system in part B, final 105.00, to provide additional guidance for adjudicating digestive disorders. Where necessary, we are adding information specific to children; however, we are repeating much of the introductory text of final 5.00 in final 105.00. This is because, for the most part, the same basic rules for establishing and evaluating the existence and severity of digestive disorders in adults also apply to children. We are making a number of changes from the NPRM in the final rules to make part B even more consistent with part A than we originally proposed. As we note below, we are also adding:

- Listing 105.02 for gastrointestinal hemorrhaging from any cause requiring blood transfusion;
- Listing 105.05A for hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy;
- Listings 105.05C, D, and E for complications of chronic liver disease;
- Listing 105.05F for hepatic encephalopathy;
- Listing 105.05G for end stage liver disease with SSA CLD and SSA CLD–P score criteria;
- Listing 105.05H for extrahepatic biliary atresia;
- Listing 105.06 for inflammatory bowel disease;
- Listing 105.07 for short bowel syndrome; and
- Listing 105.10 for the need for supplemental daily enteral feeding via a gastrostomy.

The following discussions describe only the significant provisions that are unique to the childhood rules or that require further explanation. We do not note differences like the fact that we use references to childhood listings instead of adult listings or that we use references to ''children'' instead of adults.

105.00A—What kinds of disorders do we consider in the digestive system?

Final 105.00A corresponds to final 5.00A, except that we are adding information to explain that under the childhood listings we also consider congenital abnormalities involving the organs of the gastrointestinal system.

105.00B—What documentation do we need?

The only substantive difference between final 105.00B and final 5.00B is a statement noting that we may also need assessments of a child's growth and development.

105.00D—How do we evaluate chronic liver disease?

The new guidance on chronic liver disease in final 105.00D generally corresponds to the information in final 5.00D in the adult rules, except for information specific to the complications of chronic liver disease in children and two sections (final 105.00D11b and 105.00D12) that are not in part A because they provide guidance for listing criteria that are only in the final childhood rules.

In final 105.00D11b, we provide information about the SSA Chronic Liver Disease—Pediatric (SSA CLD–P) calculation, which we use under final listing 105.05G2 for children who have not attained age 12. We explain in final 105.00D11b(iv) that we will not purchase the INR value required to calculate the SSA CLD–P score because obtaining the necessary amount of blood to perform this test in small children often requires an invasive procedure. We further explain that if we do not have an INR value for a child under 12 within the applicable time period, we will use an INR value of 1.1 for the SSA CLD–P calculation. (In final 105.00D11a, we provide the same guidelines about the SSA CLD calculation as we do in part A because the SSA CLD calculation is applicable to children age 12 to the attainment of age 18.)

In final 105.00D12, we provide guidance for applying final listing 105.05H for extrahepatic biliary atresia, a congenital disorder of the liver.

105.00E—How do we evaluate inflammatory bowel disease (IBD)?

Final 105.00E corresponds to final 5.00E. In the NPRM, we proposed a short section (proposed 105.00F4) on IBD that provided guidance for evaluating IBD under proposed listing 105.06. As in final listing 5.06 in part A, we have greatly expanded proposed listing 105.06 in these final rules, so we are also including the more detailed guidance for evaluating the expanded listing criteria of final listing 105.06 that we provide in part A for final listing 5.06.

105.00G—How do we evaluate malnutrition in children?

Final 105.00G (proposed 105.00F1) reflects changes we made to final listing 105.08, Malnutrition due to any digestive disorder. In final 105.00G1, we explain that digestive disorders may result in malnutrition and growth retardation. We also explain that we document the presence of a digestive disorder with associated chronic nutritional deficiency despite prescribed treatment using the malnutrition criteria in final listing 105.08A.

The malnutrition criteria in final listing 105.08A generally correspond to the laboratory findings we presented as examples in the introductory text, proposed 105.00F1(a)(1), F1(a)(2), and F1(a)(4). We are including them as listing criteria in final listing 105.08A in response to a public comment.

Final listing 105.08A1 corresponds to proposed 105.00F1(a)(1). However, we changed the criterion for anemia to a hemoglobin of less than 10.0 g/dL, rather than less than 8 g/dL, to be consistent with the anemia criteria elsewhere in these final listings. Final listing 105.08A2 requires low serum albumin levels and corresponds to proposed 105.00F1(a)(2). Final listing 105.08A3 corresponds to proposed 105.00F1(a)(4), except that we added the phrase ''fat soluble'' to clarify the type of vitamin deficiency we intended. We also removed the concluding phrase ''despite aggressive medical and nutritional therapy'' because the introductory paragraph of the listing requires findings ''despite continuing treatment as prescribed.'' We did not include as a listing criterion the example of intractable steatorrhea (malabsorption of dietary fats) quantified by fecal fat excretion that we had included in proposed 105.00F1(a)(3); most pediatric laboratories no longer do this type of testing, and steatorrhea will usually result in the vitamin deficiency we describe in final listing 105.08A3.

In 105.00F1b of the proposed rules, we included a paragraph discussing Body Mass Index (BMI) measurements. We explained in the preamble of the NPRM that we proposed to add this discussion because proposed listing 105.08 included criteria based on BMI measurements. (See 66 FR at 57015 and 57020.)

We are not including this paragraph in the final rules because, when we reviewed it, we realized that it did not provide guidance that would have been useful to the application of final listing 105.08 and that it could have been confusing for the following reasons:

- As in the NPRM, final listing 105.08 includes two criteria for documenting growth retardation, one for children under age 2 (final listing 105.08B1) and one for children age 2 and older (final listing 105.08B2). Only final listing 105.08B2 includes a criterion for BMI, and it refers to the CDC's latest BMI-for-age growth charts or data files. The language we included in proposed 105.00F1b did not explain this clearly.
- Furthermore, much of the language repeated what the listing already said, and we believe that the language that was not redundant of the listing was unnecessary. The first sentence defined in basic terms how to calculate a BMI; however, it was oversimplified for children.
- The proposed paragraph also referred to the fact that the CDC has determined that a BMI-for-age less than the fifth percentile meets its criteria for underweight. However, since the CDC does not calculate a figure or indicate a cutoff that it judges to be indicative of malnutrition, this guidance in the proposed rule would not have been useful for applying final listing 105.08.

In final 105.00G2, which replaces proposed 105.00F1b, we are providing information that is more relevant to the application of final listing 105.08B. We explain that we use the most recent growth charts published by the CDC. In final 105.00G2a, we explain that we use the CDC's age- and gender-specific weight-for-length charts for children who have not attained age 2. In final 105.00G2b, we explain that we use the CDC's gender-specific BMI-for-age charts for children age 2 or older. In final 105.00G2c, we explain how we calculate BMI, and in final 105.00G2d we provide the corresponding BMI formulas. Final 105.00G2c and 105.00G2d are the same as final 5.00G2a and 5.00G2b.

105.00H—How do we evaluate the need for supplemental daily enteral feedings via a gastrostomy?

Final 105.00H is a new section that provides guidance for evaluating the need for feeding gastrostomies for children under age 3 under final listing 105.10. We had previously provided for a finding of functional equivalence for children under age 3 who require a gastrostomy for feeding in § 416.926a(m)(10). We are now making that example of functional equivalence a listing and removing the example from § 416.926a(m).

105.00I—How do we evaluate esophageal stricture or stenosis?

Final 105.00I corresponds to proposed 105.00F3 and includes minor editorial changes for clarity. In this section, we provide guidance for evaluating esophageal stricture or stenosis, which we had listed in prior listing 105.03, a listing we are removing because it is a reference listing. In the final rule, we explain that these conditions may be evaluated under listing 105.08 or 105.10. We also provide guidance for adjudicating these conditions when they do not meet a listing but the child still has problems maintaining nutritional status.

105.00K—How do we evaluate impairments that do not meet one of the digestive disorder listings?

Final 105.00K corresponds to final 5.00I, except that we include two additional examples of digestive impairments relevant to children that we would evaluate in other body systems. These are the same additional examples we included in proposed 105.00E1; however, we made minor editorial changes to these examples for clarity.

How are we changing the listings for evaluating digestive disorders in children?

105.01 Category of Impairments, Digestive System

Removal of Redundant or Reference Listings

As in the adult listings, we are removing the following reference listings and other listings that are no longer appropriate:

- 105.03—Esophageal obstruction, caused by atresia, stricture or stenosis, which referred to listing 105.08;
- 105.05F—Chronic liver disease with chronic active inflammation or necrosis documented by SGOT persistently more than 100 units or serum total bilirubin of 2.5 mg percent or greater;
- 105.07B—Chronic inflammatory bowel disease with malnutrition, which referred to listing 105.08; and
- 105.07C—Chronic inflammatory bowel disease, with growth impairment as described under the criteria in 100.03. However, we are adding material to the introductory text in final 105.00G2 to address the assessment of growth retardation that is secondary to any digestive disorder.

Prior listing 105.05E, for hepatic encephalopathy, was a reference listing, referring to listing 112.02 for organic mental disorders. For the reasons we cited in our discussion of prior listing 5.05E (final listing 5.05F) above, we are including criteria for evaluating hepatic encephalopathy in the digestive listings, final listing 105.05F, instead of evaluating this impairment under the criteria for organic mental disorders. We will also evaluate the impairment in prior listing 105.05D, hepatic coma, under final listing 105.05F.

The following is a detailed explanation of the changed listing criteria where they differ from the part A listings.

Listing 105.02—Gastrointestinal Hemorrhaging From Any Cause, Requiring Blood Transfusion

Final listing 105.02, which corresponds to final listing 5.02, was not in the NPRM. We are adding it in response to a public comment described later in this preamble. The final listing is the same as final listing 5.02, except for the amount of blood transfused. In final listing 105.02, we provide a ratio of volume of blood to the child's weight, which is a more medically appropriate standard for children.

Listing 105.05—Chronic Liver Disease

Final listing 105.05A replaces prior listing 105.05C, chronic liver disease with esophageal varices. The final listing is the same as final listing 5.05A, except for the amount of blood transfused. As in final listing 105.02, we provide a ratio of volume of blood to the child's weight, which is a more medically appropriate standard for children.

Final listings 105.05C, D, E, F, and G correspond to final listings 5.05C, D, E, F, and G in part A, with appropriate changes to reflect findings and laboratory values for children. Also, final listing 105.05G includes both an SSA CLD score criterion for children age 12 and older (final listing 105.05G1) and an SSA CLD–P score criterion for children who have not attained age 12 (final listing 105.05G2).

We provide that an SSA CLD–P score of 11 or greater meets the listing. We chose this score based on the clinical severity represented by the values contained in the SSA CLD–P score, which we believe represents the degree of severity consistent with listing level severity.

For final listing 105.05G2, we require two calculations of SSA CLD–P scores, at least 60 days apart, and the scores must be calculated within a consecutive 6-month period, consistent with other provisions in these final rules.

Final listing 105.05H replaces prior listing 105.05A, inoperable biliary atresia. The new listing requires extrahepatic biliary atresia, as diagnosed on liver biopsy or intraoperative cholangiogram. We will consider children who meet this requirement to be disabled for 1 year following the diagnosis, and we will evaluate residual liver function after that period.

Listing 105.06—Inflammatory Bowel Disease (IBD)

We are redesignating prior listing 105.07, chronic inflammatory bowel disease, as final listing 105.06 for consistency with the corresponding adult listing. Final listing 105.06 is the same as final listing 5.06, except that it does not include a criterion for weight loss from baseline. This criterion is inappropriate for children because they are continually growing, and therefore do not have a ''baseline weight.'' (We can evaluate weight loss, inadequate growth, and malnutrition secondary to IBD under final listing 105.08.)

Proposed listing 105.06B required IBD with perineal or intra-abdominal complications, such as abscess, fistulae, or fecal incontinence. These complications must have been intractable despite medical or surgical treatment, and clinically documented over a 6-month period. Final listing 105.06 includes a criterion for perineal disease with draining abscess or fistula. However, we did not include fecal incontinence because final listing 105.06 includes a much wider array of complications resulting from IBD and children with listing-level impairments who have fecal incontinence would be evaluated under criteria in final listing 105.06.

Listing 105.07—Short Bowel Syndrome (SBS)

This new listing is the same as final listing 5.07 except that it applies to children. It eliminates the need for a finding of functional equivalence for children of any age who have a frequent need for a central venous alimentation catheter, as we described in the example of functional equivalence in prior § 416.926a(m)(3).

Listing 105.08—Malnutrition Due to Any Digestive Disorder

Final listing 105.08 corresponds to proposed listing 105.08; however, as we have already noted, we are including as listing criteria three of the examples of laboratory findings that would confirm chronic nutritional deficiency we had included in proposed 105.00F1a. We also removed the statement from proposed listings 105.08A and B that the required findings are ''expected to persist for at least 12 months,'' because it is unnecessary. Under our general

rules for evaluating disability, an impairment must meet the duration requirement.

Final listing 105.08 is consistent with the weight-for-length and BMI-for-age charts and data file tables from the CDC. According to the CDC, these are the recommended measurements to determine if an individual's weight is appropriate for his or her height. On May 30, 2000, the CDC updated its 1977 weight-for-length growth charts, and introduced BMI-for-age charts and tables.[1] The CDC explained that:

> These BMI-for-age charts were created for use in place of the 1977 weight-for-stature charts. BMI * * * is used to judge whether an individual's weight is appropriate for their height. * * * The new BMI growth charts can be used clinically beginning at 2 years of age, when an accurate stature can be obtained.

As we have already noted, the CDC also defines ''underweight'' in children as a BMI-for-age less than the fifth percentile, but neither the CDC nor any other recognized expert authority has published guidelines for the classification of malnutrition based on BMI. Therefore, we will continue to monitor this area, and in the meantime, continue to use our criterion of persistence of weight below the third percentile to show listing-level severity based on malnutrition for children under 2 years of age. The third percentile is generally accepted as the lower limit of the normal range for most biologic measurements, and persistence below this level would warrant evaluation and intervention. Likewise, since the current BMI-for-age charts provide percentiles, we will continue to use measurements below the third percentile as the listing-level criterion for children age 2 and older.

In response to a comment, we revised proposed listing 105.08B to indicate that we use the latest editions of the CDC's charts, which will ensure that the listing remains current if the CDC revises its charts in the future.

Listing 105.10—Need for Supplemental Daily Enteral Feeding via a Gastrostomy

In response to a public comment, we are adding final listing 105.10 for the need for a feeding gastrostomy. Because of this new listing, we no longer need the functional equivalence example in prior § 416.926a(m)(10) for a gastrostomy in a child who has not attained age 3. We are also clarifying that the gastrostomy must be used for supplemental enteral feeds on a daily basis.

[1] Centers for Disease Control and Prevention, National Center for Health Statistics. CDC growth charts: United States. May 30, 2000.

Conforming Changes

Listing 6.02—Impairment of Renal Function

For the reasons discussed in the explanation of changes for listing 5.08, Weight loss due to any digestive disorder, we are also revising listing 6.02C4 to use BMI. We are also removing the criterion for ''recent'' weight loss and replacing it with the same criterion we use in the final digestive disorder listings, a requirement for two measurements at least 60 days apart within a 6-month period.

Section 416.924b—Age as a Factor of Evaluation in the Sequential Evaluation Process for Children

We are correcting the reference in the last sentence of § 416.924b(b)(3), which should refer to the functional equivalence examples in § 416.926a(m)(7) or (8) but incorrectly designates this functional equivalence rule as § 416.924a rather than § 416.926a. Also, because we are removing two of the examples of functional equivalence, §§ 416.926a(m)(3) and (10), and redesignating the remaining examples as explained below, we are revising the reference to refer to final § 416.926a(m)(6) or (7).

Section 416.926a—Functional Equivalence for Children

We are removing paragraph (m)(3), the example of functional equivalence based on a frequent need for a life-sustaining device at home or elsewhere, because we are including the need for a central venous alimentation catheter as final listing 105.07 and because we now no longer need this functional equivalence example.

We are also removing paragraph (m)(10), the functional equivalence example of gastrostomy in a child who has not attained age 3, as it is now final listing 105.10.

Other Changes

We made many editorial changes from the NPRM for clarity in these final rules. For example, we:

- Revised many sentences to put them into active voice, to simplify them, and to use more consistent style throughout the final rules;
- Reorganized some paragraphs into a more logical order;
- Clarified several headings;
- Eliminated some redundancy from the proposed provisions; and
- Revised language for greater consistency between part A and part B.

Also, many of the paragraph designations in the NPRM were different from the way we designate paragraphs in our other body system listings. We changed those designations so they are in the same format as our other listings sections. None of these changes are substantive.

Public Comments

In the NPRM we published in the **Federal Register** on November 14, 2001 (66 FR at 57009), we provided the public with a 60-day comment period. The comment period ended on January 14, 2002. In response to that NPRM, we received letters, telefaxes, and e-mails from 11 commenters containing comments pertaining to the changes we proposed. The commenters included physicians, advocates for individuals who have disabilities, individuals who have digestive disorders, and State agencies that make disability determinations for us.

On November 8, 2004, we published a limited reopening of the comment period of the NPRM in the **Federal Register** (69 FR 64702) to request additional comments about our proposals to revise and remove chronic liver disease listings. We published this limited reopening of the comment period because we believed those proposals were significant. The comment period also lasted 60 days and ended on January 7, 2005. In response to this reopening, we received letters, telefaxes, and e-mails from 539 commenters pertaining to the changes we proposed regarding chronic liver disease. The commenters included physicians, advocates for individuals who have chronic liver disease, individuals who have chronic liver disease, and State agencies that make disability determinations for us.

In addition, on November 17, 2004, during the reopened comment period, we held an outreach meeting in Cambridge, Massachusetts. At the outreach meeting, physicians, advocates for individuals with liver disorders, and individuals who have liver disorders provided additional comments about chronic liver disease which we included in the rulemaking record for these final rules.

We carefully considered all of the written comments in response to the two **Federal Register** documents and the comments we received at the outreach meeting. Because some of them were long and many comments were similar, we have condensed, summarized, and paraphrased them below. We have tried to present all views adequately and to respond to all of the issues raised by the commenters that were within the scope of these rules. We provide our reasons for adopting or not adopting the

recommendations in the summaries of the comments and our responses below.

Proposed 5.00A and 105.00A—What kinds of disorders do we consider in the digestive system?

Comment: A commenter who has a colostomy asked us to include colostomies in our listings. He described the problems he had been having with his colostomy.

Response: We did not adopt the comment. Although we agree with the commenter that some people who have colostomies are unable to work, we did not add a listing for this because the vast majority of people who have colostomies do not experience long-term complications that would meet the 12-month duration requirement and they are able to work. However, we did include a statement in final 5.00E4 indicating that if an individual is not able to maintain nutrition due to surgical diversions of the intestinal tract, including ileostomy and colostomy, we will evaluate the impairment under listing 5.08.

Proposed 5.00B and 105.00B—What documentation do we need?

Comment: Several commenters expressed concerns about our statement in the first sentence of proposed 5.00B1 and 105.00B1 that we usually need longitudinal evidence covering a period of at least 6 months of observations and treatment, unless we can make a fully favorable decision without it. One commenter was concerned that the proposed requirement was overly burdensome, especially for low-income claimants and the homeless who are unable to access health care. This commenter noted that proposed 5.00B2 (incorrectly designated as 5.00B3 in the NPRM) provided guidance for considering medical equivalence when an impairment did not meet a listing, but was concerned that adjudicators might overlook that guidance because it was in a separate paragraph. The commenter was also concerned that administrative law judges would need more testimony from medical experts to consider the issue of medical equivalence. The commenter asked us to provide more alternatives for claimants who, through no fault of their own, are unable to access continuous health care treatment.

Some commenters stated that adjudicators may consider the 6-month requirement for observation and treatment absolute and not read the introductory text in proposed sections 5.00B3 and 105.00B2. The commenters believed that the proposed provision would require our adjudicators to defer the adjudication of significant numbers of cases with documented impairments of the digestive system until there was 6 months of evidence, even when it was obvious that those disorders were not of listing-level severity. These commenters believed that many digestive disorder cases could be fairly evaluated after 3 months of treatment and that we could give adjudicators more room for judgment. One commenter also suggested that we combine a requirement for 3 months of treatment with the establishment of a ''medical improvement expected'' diary in appropriate cases, in order to reflect advances in medical treatment and the fact that some individuals will respond to treatment.

Many commenters noted that there are some conditions that are irreversible or progressive and would not require a 6-month observation period since the likelihood of substantial improvement with these conditions is negligible.

Response: In response to these comments, we reorganized proposed 5.00B1 and 105.00B1 and removed the sentence stating that we usually need evidence covering a 6-month period of observations and treatment. We did not mean to imply that we would require evidence of 6 months of observation and treatment for all cases involving digestive disorders. We agree with the commenters that some digestive disorders are irreversible and progressive and could be fairly evaluated after 3 months of treatment, or even less. For example, final listing 5.02 does not require 6 months of evidence if the 3 required hemorrhages and transfusions occur in less than a 6-month period, as long as the transfusions are at least 30 days apart; and listing 5.05A requires only one episode of bleeding varices that require blood transfusion. In response to comments, we also added three new listings for chronic liver disease (final listings 5.05C, D, and E) that can be satisfied with documentation of the required findings on only one occasion.

We recognize that some individuals may not have access to ongoing treatment and that, because of this, they may not be able to demonstrate that their impairments meet the criteria of listings in this body system. As we explain in final 5.00C6 and 105.00C6, it may be necessary to determine whether an individual's impairment or impairments medically equal a listing or are disabling based on consideration of residual functional capacity. We do not believe that adjudicators will overlook this guidance in the introductory text because it reflects general adjudicative policy that applies to all the body system listings. Also, our adjudicators are well aware that they are required to consult the information in the introductory text when they apply the listings. We will also provide training for our adjudicators on these rules.

It may be possible that administrative law judges (ALJs) will need to consult with medical experts somewhat more frequently than they did under the prior listings, but we do not believe that there will be a large increase in this need. We expect that most cases that would have met prior digestive disorder listings and that will not meet any of the final listings will require an individualized residual functional capacity assessment and will not require such expert medical input to determine whether the individual's impairment medically equals a listing.

Comment: Another commenter noted that, while many homeless individuals infected with hepatitis C virus (HCV) do not have medical records that reflect a complete longitudinal history of medical treatment, they may have some medical evidence. The commenter said that we should contact the treating physicians instead of purchasing consultative examinations. The commenter expressed the view that a consultative examiner may not be familiar with treating people with HCV, especially those who are homeless. The commenter indicated that SSA could save financial resources and secure better evidence for use in evaluations if all community medical sources were contacted.

Response: We make every reasonable effort to secure evidence from individuals' treating physicians and other medical sources. Sections 404.1512 and 416.912 of our regulations require us to make every reasonable effort to obtain a complete medical history from an individual's medical sources. However, the regulations also explain that we will order a consultative examination if the information we need is not readily available from the records of the individual's medical sources or if we are unable to obtain clarification from the medical sources.

Proposed 5.00C and 105.00C—How do we evaluate digestive disorders under listings that require persistent or recurrent findings?

Comment: One commenter stated that our requirement that a ''recurrent'' or ''persistent'' finding must have lasted or be expected to last for 12 months is medically inappropriate for decompensated cirrhosis because continued deterioration is expected. The commenter also indicated that three events within a 6-month period with 1

month between events is medically inconsistent with the natural history of chronic liver disease because the disease is chronic and, therefore, progressive. The commenter acknowledged that some individuals with chronic liver disease experience episodes of symptoms and signs, but said that we should not have episodic requirements alone for the evaluation of the condition.

Response: We agree with the commenter that we do not need episodic requirements or evidence of persistence for all cases involving chronic liver disease. Based on this and other comments, we removed proposed 5.00C and 105.00C and added final listings 5.05C through 5.05G. By making these changes, we provide additional criteria that are appropriate for evaluating the impairments of individuals who have progressive, chronic liver disease. Final listings 5.05A, 5.05C, 5.05D, and 5.05E provide for a determination of disability based on findings on a single occasion. On the other hand, final listings 5.05B, 5.05F, 5.05G, and 5.08 include conditions that may be acute or chronic and that may respond to treatment. They contain requirements for episodes of symptoms and signs.

Proposed 5.00D and 105.00D (final 5.00C and 105.00C)—How do we consider the effects of treatment?

Comment: One commenter suggested that we discuss how the side effects of medication can affect a child's growth and social development. Another commenter noted that treatment side effects can be debilitating and can cause functional limitations that validate disability. The commenter recommended that we expand our system of disability evaluation to acknowledge and articulate how treatment can affect a child's physical, emotional, and social development, including specifying how these factors (including school performance) should be evaluated. This commenter said that we should integrate all aspects of functional development into the evaluation criteria.

Response: We did not adopt these comments because we believe that these final rules and our other rules sufficiently address issues of developmental delay and other potentially adverse effects of treatment. These final rules include general guidance to our adjudicators in final 105.00C about assessing any adverse effects of treatment. Final 105.00D4 includes a detailed discussion of the effects of treatment for chronic viral hepatitis infections, including hepatitis B and C virus. We explain that treatment for chronic viral hepatitis infections will vary considerably due to a child's age, medication tolerance, treatment response, and duration of the treatment. While we do not include the specific example of effects on ''development'' recommended by the first commenter, we do include a number of other examples of more common adverse effects of treatment in children.

In addition, we have other rules for evaluating disability in children, and these rules address the kinds of issues raised by both commenters. In § 416.924a(b)(9) of our regulations, we include a detailed explanation of how we consider the effects of treatment in children. This section explains that we consider, among other things, any functional limitations that are caused by the side effects of treatment and the frequency of the need for treatment; in the latter case, we explain that frequent therapy may interfere with a child's participation in typical daily activities, which implicitly can also affect development. Likewise, in § 416.926a we include additional guidance explaining that we consider limitations that result from treatment when we make determinations about functional equivalence (see § 416.926a(a)). In the sixth domain of functioning, ''health and physical well-being,'' we consider the cumulative physical effects of physical or mental impairments and their associated treatments or therapies on a child's functioning (see § 416.926a(1). We also explain that medications and other treatments a child receives may have physical effects that also limit his or her performance of activities (see § 416.926a(a)(3)).

Comment: One commenter disagreed with the proposed guidance on parenteral and specialized enteral nutrition. The commenter stated that individuals who have intravenous or gastrostomy tubes require special equipment and frequently require multiple feedings a day that may entail a significant amount of time. In the commenter's opinion, this is so intrusive that individuals who require parenteral or specialized enteral nutrition to avoid debilitating complications of a disease should be considered not able to work, and disability should be established if the 12-month duration requirement has been, or is expected to be, met.

Response: We partially adopted the comment. There is a wide range in the nature and severity of underlying diseases that require parenteral or supplemental enteral nutrition, the type of delivery and scheduling of administration of such nutrition, and potential related complications. Many individuals who receive home parenteral or supplemental enteral nutrition have a reasonably normal lifestyle, including regular employment. Therefore, we do not think it appropriate to presume disability in all individuals who need such treatment; we must evaluate most situations on a case-by-case basis. However, we did agree that in certain instances the need for parenteral nutrition can be disabling. Therefore, we added final listings 5.07 and 105.07 for short bowel syndrome when post-operative nutritional needs cannot be met orally and an individual requires daily parenteral nutrition via a central venous catheter. We also added a criterion based on the need for daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter in final listings 5.06 and 105.06 for IBD.

As a consequence of the changes we made in response to this comment, we are also removing two of the examples of functional equivalence in § 416.926a(m). Section 416.926a(m)(3) provided for a finding of functional equivalence for children of any age who have a frequent need for a life-sustaining device, ''e.g., central venous alimentation catheter.'' Section 416.926a(m)(10) provided for a finding of functional equivalence for children who have not attained age 3 and who have a gastrostomy. Therefore, in these final rules, we are removing functional equivalence examples (m)(3) and (m)(10) because we no longer need them, as we explained earlier in this preamble.

If we determine that the impairment does not meet or medically equal one of these listings, we will consider the need for parenteral or supplemental enteral nutrition via a gastrostomy in our residual functional capacity assessment or functional equivalence determination, especially in the kinds of situations described by the commenter. For example, the functional equivalence domain for children called ''health and physical well-being'' requires us to consider the cumulative physical effects of physical or mental impairments and their associated treatments or therapies on the child's functioning (see § 416.926a(l)).

Proposed 5.00F and 105.00F—What are our guidelines for evaluating specific digestive disorders? (Final 5.00D and 105.00D—How do we evaluate chronic liver disease?)

Comment: Several organizations made suggestions for specific language changes to the introductory text of the

listings (proposed 5.00 and 105.00). Many commenters asked us to expand our discussion of the signs, symptoms, and complications of chronic liver disease. They asked us to list symptoms, such as chronic fatigue, chronic indigestion, diarrhea, constipation, and sleep disturbances. Commenters also proposed that we add specific laboratory findings to the introductory text, such as decreased platelets and acid-base imbalances. They suggested that we should take into account the frequency of extrahepatic manifestations resulting from chronic liver disease and factor them into the medical evaluation.

Response: We partially adopted these comments by expanding the introductory text to provide additional adjudicative guidance on symptoms and signs of chronic liver disease. We are providing general information on symptoms and signs in final 5.00D3 and 105.00D3, and, where appropriate, specific information about symptoms and signs of particular chronic liver diseases. For example, in final 5.00D4c(ii) and 105.00D4c(ii), we provide examples of symptoms associated with the adverse effects of treatment for chronic hepatitis C virus infection, and in final 5.00D4d and 105.00D4d, we also provide examples of extrahepatic manifestations of chronic viral hepatitis by body system. We did not adopt all the specific language commenters requested because certain symptoms, such as indigestion, diarrhea, and constipation, are generally not features of chronic liver disease. However, we did include in final 5.00D3c and 105.00D3c decreased platelet count in the list of laboratory findings associated with chronic liver disease, and we indirectly referenced acid-base imbalances by adding increased ammonia levels as another laboratory finding.

Comment: One commenter suggested that we add the phrase ''or the remainder of an individual's natural life'' to the first sentence of proposed 5.00F2 (final 5.00D1). This sentence described chronic liver disease and explained that it persists for more than 6 months and is expected to continue for at least 12 months.

Response: We did not adopt the comment. The issue in our initial disability determinations and decisions under the listings is whether the individual has an impairment that prevents him or her from engaging in any gainful activity (or in a child, that causes ''marked and severe functional limitations'') and that has lasted or can be expected to last for a continuous period of 12 months or that is expected to result in death. We are required by law to reevaluate the disability status of all individuals who qualify for disability benefits and this applies even to people who have permanent impairments. Therefore, there would be no practical reason for us to add the phrase requested by the commenter.

Comment: One commenter recommended that we delete the word ''function'' in proposed 5.00F2d and 105.00F2e when referring to liver tests because liver enzymes are not liver function tests.

Response: We adopted the comment in final 5.00D3c and 105.00D3c.

Comment: One commenter suggested we delete the word ''minimal'' when referring to ascites in proposed 5.00F2(d) and 105.00F2(e) (final 5.00D6 and 105.00D6) and that we change it to ''small volume.'' The commenter also suggested that we delete ''and not on physical examination'' in this same section to more clearly indicate that we are referring to incidental and clinically insignificant findings of ascites found on imaging studies alone.

Another commenter indicated that ascites should be evident on physical examination and not identified solely by an imaging procedure that might show clinically insignificant findings of ascites. This commenter also suggested listing criteria based on intractable ascites, documented on physical examination as moderate to severe, or hydrothorax, poorly controlled by or unresponsive to diuretic treatment, or requiring paracenteses for control.

Response: We agree with the commenters that current imaging techniques are capable of detecting even minimal amounts of ascites before detection may be possible on physical examination. However, the criteria of proposed listings 5.05B2 and 105.05B2 did not base severity solely on the presence of ascites detected by physical examination or by imaging studies; nor do these final listings. To meet the severity requirement, the laboratory findings in final 5.05B2 and 105.05B2 must also be present. If the laboratory findings are at the level specified in the listing, it is not necessary to quantify the ascites because there will be sufficient information to show that the individual is disabled. Therefore, we did not adopt the comment to change the quantifier from ''minimal'' to ''small volume'' ascites; instead, we removed it.

We adopted the second commenter's suggestion to include criteria in final listing 5.05B and 105.05B for hydrothorax because ascitic fluid can collect in the chest cavity and result in a very serious impairment. We did not adopt the other recommendation that we characterize listing-level ascites as ''moderate to severe,'' because these terms are subject to varying interpretations and their use would not promote consistent adjudication.

Comment: One commenter suggested that we provide detailed information about a number of extrahepatic manifestations and complications of chronic liver disease and suggested additional language for proposed 5.00F (final 5.00D).

Response: Based on this and other comments, we added language in final 5.00D7 through D11 and the corresponding paragraphs in 105.00. These sections provide guidance relevant to the application of the new listings we are adding for complications of chronic liver disease; that is, final listings 5.05C through G and 105.05C through H. We also provide information on extrahepatic manifestations of hepatitis B and C in final 5.05D4d and 105.05D4d. The additional information we provide is relevant only to application of the listings, and therefore, does not include the amount of detail this commenter suggested.

Comment: Several commenters requested that we provide a listing for individuals placed on a liver transplant list. They submitted proposals for the introductory text to explain this suggested listing.

Response: We did not adopt the suggestion of placement on a liver transplant list alone as a listing because the threshold criteria for placement on a transplant list vary widely throughout the country and because individuals may be placed on a list well before they have listing-level impairments. However, based on this and other comments we added final listings 5.05G and 105.05G for end stage liver disease documented by particular scores determined using the SSA Chronic Liver Disease (SSA CLD) calculation and SSA Chronic Liver Disease-Pediatric (SSA CLD–P) calculation. We based these calculations on the Model for End Stage Liver Disease and the Pediatric End Stage Liver Disease (MELD and PELD) scales that were developed by the United Network of Organ Sharing for prioritizing patients waiting for liver transplants based on statistical formulas for predicting mortality from liver disease.

Comment: One commenter noted that liver patients regularly have laboratory studies to track their liver function. Any decline in function is evident almost immediately and these laboratory studies are often done bi-weekly, or weekly in some cases. The commenter said that we should be able to use the laboratory findings rather than wait until a patient's condition declines to

the point that he or she needs a liver transplant.

Response: We partially adopted the comment. Although we have indicated that laboratory studies may not be a good indicator of disability, since there may be a poor correlation between the studies and the severity of liver disease, we believe that some laboratory findings can be indicative of listing-level severity for certain disorders, such as spontaneous bacterial peritonitis (final listings 5.05C and 105.05C), hepatorenal syndrome (final listings 5.05D and 105.05D), hepatopulmonary syndrome (final listings 5.05E and 105.05E), and end stage liver disease (final listings 5.05G and 105.05G).

Final Listing 5.02—Gastrointestinal Hemorrhage From Any Cause, Requiring Blood Transfusion

Comment: Proposed listing 5.02 specified that at least 2 units of blood must be transfused per episode. One commenter expressed concern that different physicians and different religious preferences can dictate when and how much blood is transfused. The commenter said that it appeared more reasonable to use hematocrit levels, which are standardized, instead of a more subjective and less standardized method based on the number of units transfused.

Response: We did not adopt the comment to use a hematocrit level in this listing because it takes time for the hematocrit to equilibrate following rapid blood loss. We also did not adopt the comment to remove the 2-unit requirement for the amount of blood transfused per episode in final listing 5.02. As we explained earlier, we chose 2 units of blood because this is the minimum amount of blood that is usually transfused.

We recognize that there are individuals who may object to transfusions. In such cases, their impairments cannot meet the requirements of any listing that includes a criterion for a transfusion. However, it is certainly possible for a person who refuses transfusions to be found disabled under our other rules for determining disability.

Comment: One commenter noted that in proposed listing 5.02 we stated that all incidents within a consecutive 14-day period constitute one episode, but in proposed 5.00C2 we also stated that there must be at least 1 month between events (incidents). The commenter asked us to clarify these requirements because it seemed that all events within a 30-day period should constitute one episode.

Response: We clarified the requirements by deleting the sentence in proposed listing 5.02 that referred to episodes within a 14-day period because it could have been confusing and was not necessary for correctly applying the listing. Although our intent was to explain that several bleeds may occur during a single episode, listing-level severity is based on hemorrhages that require transfusions and not the actual number of bleeds per episode. We require 30 days between hemorrhages that require transfusion in order to establish that there are separate events and that the condition is chronic.

Final Listings 5.05 and 105.05—Chronic Liver Disease

Comment: One commenter recommended that we place the study ''endoscopy'' before ''x-ray'' in listing 5.05A because 95 percent of diagnoses for varices are made by endoscopy.

Response: We adopted the comment.

Comment: We received many comments asking us to change the headings of listings 5.05 and 105.05. Commenters suggested eliminating the words ''and cirrhosis of any kind,'' stating that ''cirrhosis'' is chronic liver disease. Commenters also pointed out that individuals may have chronic liver disease but not necessarily cirrhosis.

Response: We adopted the comments and removed the reference to ''cirrhosis'' from the headings of the two listings.

Comment: One commenter stated that the definition of cirrhosis can be subjective. The commenter said that one doctor who reads a tissue sample may diagnose fibrosis and another doctor may diagnosis cirrhosis. This commenter stated he had had debilitating symptoms before he officially had cirrhosis.

Response: We do not agree that the definition of cirrhosis is subjective. Cirrhosis is a disorder defined by pathology. Fibrosis is an early form of scarring. Cirrhosis is late-stage disease and readily distinguishable by pathologists from fibrosis. We do agree, however, that individuals can have debilitating problems from chronic liver disease before they develop cirrhosis. As we have noted in a number of places throughout this preamble, we have expanded and clarified the final rules to ensure that we identify people without cirrhosis who should qualify under these final listings.

Comment: Many commenters noted that the proposed changes for chronic liver disease contained fewer criteria (physical examination, laboratory, or imaging tests) to establish disability than did the prior listings. They expressed concern about ''compressing'' prior listings 5.05 B, C, D, E, and F into proposed listing 5.05B, which contained only two sets of severity criteria. Some commenters said that the proposed listings were vague and too narrow in scope. Commenters believed that this would make our determinations more restrictive and perhaps erroneous. They urged us to expand the medical evaluation criteria to more accurately reflect the pathophysiology of chronic liver disease. The commenters believed that the listings should be more specific and inclusive with regard to signs, symptoms, complications, treatment, and metabolic and functional factors to make the evaluation of chronic liver disease more on par with HIV criteria because hepatitis C is a systemic illness that encompasses a broad spectrum of diseases similar to HIV infection.

Response: We adopted many of these comments. We significantly expanded the listing criteria for chronic liver disease. For example, we expanded proposed listings 5.05A and 105.05A to include hemorrhaging from gastric or ectopic varices and portal hypertensive gastropathy. We also expanded proposed listings 5.05B and 105.05B to include hydrothorax as well as ascites. We added four listings in parts A and B based on suggestions from commenters: Final listings 5.05C, D, E, and G, and 105.05C, D, E, and G. We also replaced the prior reference listing for hepatic encephalopathy with a stand-alone listing for this complication of chronic liver disease (final listings 5.05F and 105.05F).

Analogous to the detailed guidance we provide about HIV infection in 14.00D and 114.00D of our listings, we have greatly expanded the introductory text to include detailed information on chronic viral hepatitis infections in final 5.00D4 and 105.00D4. We provide information about the symptoms, signs, and complications of chronic hepatitis B and C virus, and include information about the types of treatment for these infections and the common adverse effects of this treatment. We have also added information on extrahepatic manifestations of hepatitis B and C virus by body systems.

We did not add all of the suggested complications or extrahepatic manifestations of chronic liver disease because most respond to prescribed treatment and they are generally very rare. Also, some of the suggested extrahepatic syndromes are multi-causal, may be unrelated to the liver disease, and poorly correlate with the degree of liver destruction. Very serious extrahepatic manifestations that we did not list in these final rules can be

evaluated under the affected body system. Lesser manifestations are evaluated in the residual functional capacity assessments or functional equivalence evaluations later in the appropriate sequential evaluation process for adults or children. (We describe the sequential evaluation process later in this preamble.)

Comment: Several commenters suggested we include a classification system, such as the Child-Turcotte-Pugh score, which has a refined scoring system and has been validated for years as predictive of mortality. This score indicates cirrhosis as ''compensated'' and ''decompensated.''

Another commenter suggested that we should not use the Child-Turcotte-Pugh score because it does not pick up some disabilities, but we should use the MELD and PELD scoring systems which have replaced it.

Response: We partially adopted the suggestion to use a classification system by including an SSA CLD score criterion in final listing 5.05G, and SSA CLD and SSCLD–P score criteria in final listings 105.05G1 and G2. The SSA CLD and SSA CLD–P calculations are based on the calculations for the MELD and PELD scores, but we made minor changes to these calculations to make them more appropriate for determining disability. We did not base the SSA CLD–P calculation on the Child-Turcotte-Pugh score because it has been superseded by the PELD in clinical practice.

Comment: Several commenters were concerned about our proposal to remove prior listing 5.05B, for performance of a shunt operation for esophageal varices.

One commenter noted there are still problems that can occur with the TIPS shunting procedure, such as occlusion, infection, or failure. The commenter noted that TIPS shunting does not have any bearing on the severity of the condition that required the shunt. The commenter also indicated that, although the shunt will help relieve the pressure causing the hemorrhage, it does not bring about a recovery or improvement of the liver disease itself.

The same commenter stated that, after a TIPS procedure, the blood is not being filtered by the liver, but is bypassing liver function, and that blood toxicity is an issue. The commenter noted that TIPS prevents or postpones the next big bleed, but does not cure the underlying disease, usually cirrhosis. The debilitating symptoms are not eliminated and the patient is unable to perform work or normal lifestyle functions.

Response: We did not adopt the comments asking us to keep prior listing 5.05B. As we indicated in the preamble to the NPRM, more modern types of procedures, such as TIPS, are less risky and can be performed before the condition becomes serious enough to meet the level of severity required by our listings. Therefore, we cannot presume that everyone who has had a TIPS procedure is disabled. However, we will evaluate the severity of the underlying chronic liver disease under final listing 5.05, and if it does not satisfy the requirements of the listing, we will evaluate the effects of any debilitating symptoms when we assess residual functional capacity at later steps in the sequential evaluation process.

We do agree that complications of TIPS may occur. However, if there are complications, immediate medical attention would be required, and the complications would not last or be expected to last for 12 months.

We do not agree with the comment that blood is not being filtered by the liver after a TIPS procedure. Portal pressure is reduced by the TIPS procedure, which connects the portal vein to the hepatic vein using a stent (shunt); however, there is still some blood that filters through the liver.

Comment: Many commenters disagreed with our proposal to remove prior listings 5.05E and 105.05E for hepatic encephalopathy. They noted that this condition is directly related to end stage liver disease and affects an individual's ability to work due to manifestations such as confusion, poor memory, and lack of concentration. Many commenters also recommended that we include criteria for evaluating hepatic encephalopathy in the digestive disorders listings rather than evaluating the condition in the mental or neurological body systems. Another commenter noted that TIPS can cause encephalopathy, and said that doing away with listings for shunts and hepatic encephalopathy was not a good idea.

Response: We adopted the comments. Although we are still removing prior listings 5.05E and 105.05E because they were reference listings that only referred to the mental disorders listings, we are adding new listings for hepatic encephalopathy that contain specific evaluation criteria, final listings 5.05F and 105.05F. These final listings include criteria for the behavioral or cognitive manifestations of hepatic encephalopathy in combination with TIPS or any surgical portosystemic shunt or in combination with a specific clinical or laboratory finding. We are also providing guidance in final 5.00D10 and 105.00D10 of the introductory text for using the new listings.

Comment: We received many comments regarding the use of liver biopsies in the evaluation of chronic liver disease. Commenters stated that individuals with chronic liver disease may suffer from a multitude of symptoms and have little evidence of injury to their liver, while others may have few symptoms, even with extensive cell damage on liver biopsy. Therefore, histological findings may not correlate with functional capacity. Others noted that extrahepatic manifestations of chronic liver disease cannot be found on liver biopsy, yet these manifestations are symptomatic and limiting.

Also, in an apparent reference to our proposal to remove the requirement for confirmation of chronic liver disease by liver biopsy in prior listing 5.05F, commenters agreed that a biopsy should not be mandatory. However, they indicated that the results of a biopsy could help to assess whether an individual has cirrhosis, particularly early cirrhosis, since symptoms may not be substantiated by blood tests or physical examination.

Response: We agree with the commenters that a liver biopsy is useful in diagnosing cirrhosis, and in final 5.00D3c and 105.00D3c, we explain that biopsy may demonstrate the degree of liver cell necrosis, inflammation, fibrosis, and cirrhosis. We also agree with the commenters that a liver biopsy is not a good predictor of the severity of symptoms of chronic liver disease or their effect on functioning. Therefore, as we explained earlier, we have removed prior listing 5.05F, which was based in part on confirmation of chronic liver disease by liver biopsy. We will continue to consider liver biopsy reports when they are part of the existing medical records in combination with all the other evidence in the case record.

Comment: Several commenters stated that many of the medications and procedures used to treat the symptoms of liver disease, such as higher dose diuretics, repeated large-volume paracenteses, and placement of TIPS for bleeding esophageal varices, have side effects that we should consider. The commenters noted that treatment can lead to major electrolyte or renal problems.

Response: We agree that the effects of treatment must be considered in assessing digestive impairments. In final 5.00C and 105.00C, we provide general guidance for how we consider the effects of treatment for all impairments in this body system. In final 5.00D4 and 105.00D4, we provide specific guidance

about how we consider the effects of treatment for chronic viral hepatitis infections.

Also, if an impairment does not meet or medically equal a listing, we continue to consider the effects of treatment on the individual's ability to function when we assess residual functional capacity, or for children, when we assess functional equivalence.

Comment: Several commenters suggested that we add documented portal hypertension to listing 5.05A and 105.05A.

Response: We adopted the comment.

Comment: One commenter suggested that proposed listing 105.05A was more restrictive than proposed listing 5.02 for adults, with no corresponding childhood listing 105.02 for children. The commenter suggested that we include a comparable listing for children based on three gastrointestinal bleeds requiring transfusion in a 6-month period due to any disease process, not just esophageal varices.

Response: We adopted the comment and added a corresponding childhood listing 105.02 with essentially the same provisions as in final listing 5.02.

Comment: Many commenters recommended that we delete the word ''massive'' from proposed listings 5.05A and 105.05A. They also suggested including other sites of bleeding besides the esophagus under listing 5.05A, specifically bleeding from gastric and ectopic varices, and portal hypertensive gastropathy.

Response: We adopted the comments and made corresponding changes to final 5.00D5 and 105.00D5 of the introductory text which provide guidance for applying listings 5.05A and 105.05A. We also changed the proposed criteria of these listings, as we explain in our response to the next comment.

Comment: Many commenters opposed the requirement in proposed listing 5.05A that an individual receive 5 units of blood in order for his or her impairment to meet the requirement for a massive hemorrhage.

One commenter stated that it would be more reasonable to simply require a ''significant hemorrhage.'' This commenter noted that any transfusion is significant.

Another commenter said that specifying the number of units transfused could not be supported because the size of the individual, the protocol of the hospital, the timeliness of the intervention, and other factors could influence the amount of blood transfused. This commenter doubted that the prognosis for an individual with bleeding varices who receives 4 units is significantly better than for an individual who receives 5 units. The commenter thought that, since physicians and hospitals are reluctant to transfuse blood, any blood transfusion should suffice or the matter should at least be left to medical judgment.

Another commenter said that a transfusion of ''multiple'' units of blood in conjunction with other interventions in an attempt to restore hemodynamic stability should suffice and that there should be some latitude for medical judgment in this listing.

Another commenter stated that we should include other criteria to define a hemodynamically significant bleed, such as at least a 2-unit bleed, or a drop in blood pressure and increase in pulse rate. This commenter also suggested changing the wording from ''hemodynamic instability'' to ''hemodynamically significant bleed'' in the listing and the introductory text.

Response: We partially adopted the comments. We agree that the proposed rule was too severe. Therefore, we revised the listing so that the primary criterion for listing-level severity is hemorrhaging that results in hemodynamic instability and requires hospitalization for transfusion. Since the minimum amount of blood a physician will usually transfuse in adults is 2 units, we used this amount in the listing.

In final 5.00D5, we also adopted some of the language suggested by commenters to describe hemodynamic instability, including pallor, diaphoresis, rapid pulse, low blood pressure, postural hypotension, and syncope. (We also provide brief definitions of the more technical medical terms on this list.) We do not indicate, as we did in the NPRM, that hemodynamic instability may require multiple transfusions because final listing 5.05A requires only one transfusion.

We made similar changes in the part B section for children, but provided a rule for documenting appropriate transfusion volumes based on body weight.

Comment: One commenter noted that some people could not meet listing 5.05A because they may have many large varices clipped. These individuals would be in serious danger and disabled without ever bleeding.

Response: We agree that an individual who has had prophylactic banding of varices without a bleed would not meet the requirements of final listing 5.05A. However, one of the major complications of cirrhosis with portal hypertension is bleeding varices; therefore, a criterion for hemorrhaging is appropriate in these listings. An impairment that does not meet the requirements of 5.05A because varices have been clipped may still meet the requirements of final listing 5.05B through 5.05G or be disabling on another basis.

Comment: One commenter stated that the mortality rate associated with variceal bleeding has decreased over the last several years with advances in therapy. If an individual goes more than a year without recurrent bleeding, he or she is back at baseline and has only a 25 percent risk for bleeding. The commenter recommended that we determine disability at that point by the state of decompensation of the liver rather than the risk of bleeding.

Response: All of the criteria in final listings 5.05 and 105.05 are based on the state of decompensation of the liver rather than the risk of bleeding. The requirement under 5.05A for hemorrhaging that results in hospitalization and transfusion reflects one of the major complications of chronic liver disease. When we determine whether an impairment that met 5.05A continues to be disabling following the 1-year period of disability, we evaluate any residual impairment(s), including bleeding and other complications of chronic liver disease.

Comment: One commenter stated that the proposed language for the length of disability under listings 5.05A and 105.05A (that is, ''for 1 year following the last documented massive hemorrhage'') did not work. The commenter suggested that the correct standard has to be the state of decompensation of the liver, not a fixed period of time.

Response: We did not adopt the comment. As we explained in the NPRM, we changed the period for which we would presume the impairment is disabling from 3 years to 1 year because of newer techniques in the treatment of esophageal varices. (See 66 FR at 57013.) The same logic would hold for other bleeds as well.

Also, it is important to remember that the 1-year rule does not mean that disability automatically ends 1 year following the last documented transfusion (we removed the description ''massive hemorrhage'' as we explained earlier). Our rule is only that after 1 year we must consider whether the impairment is still disabling. Also, our existing rules allow our adjudicators to decide that we will not review a case until a date later than 1 year after the qualifying event (in this case, the last documented transfusion), if the medical evidence supports a conclusion that the disability will continue for longer than 1 year.

Comment: One commenter objected to the criterion in proposed listing 5.05B2a for a cutoff level for serum albumin depletion, stating that the actual serum albumin level is dependent upon many factors, such as hydration and the degree of portal hypertension. The commenter suggested that we change the listing criterion to ''an associated decrease in serum albumin.''

Response: We did not adopt the comment. A serum albumin level of 3.5 g/dL is normal. Even though a level between 3.0 g/dL and 3.5 g/dL may indicate an abnormality, it is does not reflect listing-level severity. A level of 3.0 g/dL or less is recognized by hepatologists as indicative of loss of liver biosynthesis.

We set the laboratory values in these listings, such as the serum albumin level in 5.05B2a, at a level that reflects very serious impairment because we use the listings only to deem individuals disabled without considering any other factors that may contribute to their inability to work; that is, their residual functional capacity, age, education, and work experience. However, the establishment of these levels does not mean that individuals whose impairments do not satisfy the criteria of the listing are not disabled; it only means that we do not presume that they are disabled under the listing. We may still find that the impairment is disabling based on an individualized assessment of its effects on the individual's functioning.

Comment: One commenter suggested that we include a criterion for malabsorption with involuntary weight loss of 10 percent or more from baseline in the absence of a comorbid condition that could explain the findings.

Response: We did not adopt the comment because malabsorption is not a common feature of chronic liver disease. However, individuals with chronic liver disease and the appropriate degree of weight loss can meet the requirements of final listings 5.08 or 105.08.

Comment: Several commenters suggested that we change the measure of coagulation studies from prothrombin time to International Normalized Ratio (INR) as many laboratories do not report the prothrombin time in terms of seconds, but do report the INR.

Response: We adopted the comment.

Comment: Several commenters suggested that we include hepatic malignancy as a criterion in listings 5.05 and 105.05, noting that many liver diseases result in hepatocellular carcinoma.

Response: We did not adopt the comment because we already have listings for malignant tumors of the liver, listing 13.19 for adults and listing 113.03 for children. However, in response to this comment, we added a cross-reference to listing 13.19 in final section 5.00D1 and to listing 113.03 in final section 105.00D1.

Comment: Several commenters stated that some hepatic conditions, such as Budd-Chiari syndrome, may not include cirrhosis or ascites, but are disabling and should be included as conditions for determining eligibility for disability benefits.

Response: We did not add all the specific conditions mentioned by the commenters to the listings. However, as already explained, we did add several criteria to final listing 5.05 and 105.05 to expand the scope of those listings and to address additional manifestations of chronic liver disease. We also expanded the introductory text in 5.00D2 and 105.00D2 to provide examples of chronic liver disease that should be considered under the listings when they result in the complications specified in the listings. We added guidance regarding the effects of the extrahepatic manifestations of chronic liver disease that should be considered under the requirements of other body systems or at later steps in the sequential evaluation process when the impairment does not meet or medically equal a listing in the digestive disorders body system.

Comment: One commenter noted that we proposed to remove the laboratory values from prior listings 5.05C and 5.05F and asked why we did not propose to delete the laboratory values in proposed listing 5.05B. The commenter recommended that we delete the values from listing 5.05B as well.

Response: We did not adopt the comment. As we explained in the NPRM (66 FR at 57013) and have explained earlier in this preamble, we did not propose to delete the laboratory values in proposed listing 5.05B because they are specific indicators of the severity of the deterioration of liver function in that listing. Serum albumin level is a good indicator of liver biosynthesis and it correlates with the severity of ascites. In addition, blood coagulation disorders resulting from chronic liver disease are indicative of the severity of the liver dysfunction. However, as we explained earlier in this preamble, we are providing a criterion for an elevated INR as a measure of the body's ability to regulate coagulation, rather than a prolongation of prothrombin time as in the prior and proposed listing, because INR is a more widely used study than prothrombin time.

Comment: Another commenter believed that our proposal to eliminate prior listing 5.05C, which required chronic liver disease with elevated serum total bilirubin, would be a ''great disservice'' to individuals with primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), and autoimmune hepatitis (AIH). The commenter noted that elevated serum total bilirubin levels and pruritis associated with these conditions are very real problems. Also, a commenter noted that most primary care doctors are not going to run studies other than the serum total bilirubin.

Response: Even though serum total bilirubin studies may be readily available in the medical records from primary care physicians, we are removing prior listing 5.05C because, as we explained earlier, this laboratory finding alone is not a good indicator of impairment severity or an individual's ability to function. However, serum total bilirubin is one of the three laboratory values we use to calculate the SSA CLD score for final listing 5.05G.

In response to this comment, we are providing a list of examples of chronic liver disease in final 5.00D2. The list includes PBC, PSC, and AIH, and will remind adjudicators that these conditions can be evaluated under final listing 5.05.

Comment: One commenter stated that doctors are finding that low platelet counts are an indicator of portal hypertension and that they should be added to the criteria for listings 5.05 and 105.05. The commenter noted that patients are concerned about the amount of physical activities they can perform with low platelet counts and abnormal coagulation.

Response: We do not include low platelet counts as stand-alone criteria for listing-level severity because there is a wide statistical variation in platelet counts, and there is no specific level at which individuals will subsequently bleed. We consider any functional consequences, such as limitations in an individual's ability to perform physical activity, when we assess residual functional capacity in adults and functional equivalence in children.

However, in response to this comment, we added a reference to abnormal coagulation studies, including an increased INR level and decreased platelet counts, in our list of laboratory studies associated with chronic liver disease in final 5.00D3c and 105.00D3c. We explain that elevated INR level does indicate loss of synthetic liver function, as well as increased likelihood of cirrhosis and associated complications. We also include an elevated INR level

in the criteria of listings 5.05B and 105.05B.

Comment: Proposed listings 5.05B and 5.06 contained criteria that required specific findings to occur during a consecutive 6-month period. Commenters believed that our proposal to change the requirement that ascites persist for 5 months in prior listing 5.05D to a requirement for 6 months in proposed listing 5.05B seemed arbitrary and unfair because not all impairments fit neatly into 6-month blocks. (There was no 6-month requirement in prior listing 5.06.) The commenters believed that we changed the listing simply to coincide with an arbitrary timeframe without regard for long-held understanding of medical severity. One commenter believed that the period was excessive because clinically significant ascites for 3 months despite treatment represents serious liver disease.

Another commenter questioned how we would handle cases in which the appropriate findings persist consecutively over a 2- to 5-month period, improve for a few months, and then recur for a few months. The commenter asked if a case involving multiple recurring periods, none of which individually lasts up to 6 consecutive months, could equal either of these listings.

Response: As we explained in the NPRM, ''[i]n our experience, requiring 6 months of persistent findings enables us to make a more reliable prediction of listing-level severity.'' (See 66 FR at 57013.) Requiring findings from at least two evaluations, at least 60 days apart, within a consecutive 6-month period allows us to document the recurrent or persistent nature of many of these impairments and is a more reliable indicator that the impairment will be disabling for 12 consecutive months. When these listing requirements are satisfied, we can generally conclude that the impairment will be disabling for 12 consecutive months.

In the two examples provided by the commenters (that is, clinically significant ascites for 3 months despite treatment, or findings persisting for 2 to 5 months that improved for a few months and then recurred), the impairments would meet the listing if there was evidence showing the required findings on two evaluations spaced at least 60 days apart. These examples show that we do not necessarily need 6 months of evidence to find that an impairment meets the listing. Also, as we have already noted, if the impairment does not meet the criteria of any of these final listings, it may meet the criteria of a listing in another body system, medically equal a listing, or meet the definition of disability later in the sequential evaluation process.

Comment: One commenter believed that we should not require documentation of ascites by both physical examination and appropriate medically acceptable imaging under proposed listings 5.05B2 and 105.05B2. The commenter stated that imaging studies are not always available and that, if ascites is observable on examination and the serum albumin or coagulation studies criterion in the listing is fulfilled, it seems unnecessary to also require documentation by imaging. Another commenter noted that it is difficult to demonstrate ascites in obese people by physical examination, and requiring both types of documentation could reduce the chance that an individual who is obese would benefit from this listing.

Another commenter stated that our proposed listing 5.05B criteria did not quantify the amount of ascites and that we should be evaluating significant ascites.

Response: We adopted the first two comments by providing in final listing 5.05B2 that ascites or hydrothorax can be demonstrated by appropriate medically acceptable imaging ''or'' by physical examination. Since the required laboratory findings in final listings 5.05B2 establish the severity of the impairment under the listings, we agree that there is no need to require documentation of ascites both on physical examination and on imaging. Because of this change in the final rules, individuals with obesity will be able to meet this listing with ascites demonstrated on imaging techniques alone, provided they meet the other criteria of the listing.

Because of this comment, we also reviewed the same criterion in proposed listing 105.05. For consistency, and because it is medically appropriate, we included the same requirements for children in final listing 105.05B as we do for adults in final listing 5.05B. We also restored the criterion from prior listing 105.05B for an associated serum albumin of 3.0 g/dL or less and added a criterion for an INR of 1.5 consistent with final listing 5.05B. This will ensure that the ascites is a sign of chronic liver disease.

Because we are requiring the associated laboratory studies with the ascites to demonstrate listing-level severity, we will not need to quantify the amount of ascites.

Comment: One commenter recommended that we not delete listing 105.05A, inoperable biliary atresia, and require children to prove disability in other ways.

Response: We adopted the comment. In final listing 105.05H, we have clarified that the listing applies only to extrahepatic biliary atresia, thus excluding other types, such as intrahepatic biliary atresia. We are no longer using ''inoperable'' to describe the condition, because by definition, extrahepatic biliary atresia cannot be remedied with surgery except by liver transplantation; the portoenterostomy procedure usually performed in the first 3 months of life is only palliative.

Comment: One commenter believed that our requirement for prolongation of the prothrombin time of at least 2 seconds in proposed listing 5.05B2(b) was medically unreasonable and might be excessive. The commenter suggested that any reading above the normal value for the reporting laboratory should qualify.

Response: We disagree with the comment; however, we have removed the proposed criterion for measurement of prothrombin time and instead provided a criterion for INR in final listing 5.05B2 because INR is a more widely used study than prothrombin time. As we explained earlier, because we use the listings to deem individuals disabled, we must set laboratory values in the listings at levels that reflect very serious impairment.

Comment: One commenter suggested that we include in listing 105.05 consideration of poor school performance, difficulties in play, and growth and developmental delays. The commenter gave examples of developmental delays due to ascites, such as inability to roll over.

Response: We did not include this information in the listing, but in response to this comment we did note in final 105.00D3 in the introductory text that the manifestations of chronic liver disease may include developmental delays or poor school performance. The issues raised by this comment are more appropriately addressed when we make functional equivalence determinations under § 416.926a, where we provide detailed, age-specific guidelines for evaluating limitations in school, play, and various other developmental issues.

Comment: Many commenters stated that we should include a separate listing for chronic hepatitis B and C. Some suggested that we do not recognize the hepatitis C virus as a disability and they believed that it is ''unacceptable'' to evaluate individuals with chronic hepatitis C virus under the chronic liver disease listings. Some commenters thought that our proposals would

restrict individuals with hepatitis C from receiving benefits. One commenter said that our proposed changes did not take into account knowledge gained in the last 20 years regarding the hepatitis C virus. Some commenters thought we were removing hepatitis C and all liver diseases from the listings, while others suggested that we wrote the chronic liver disease listings only for alcoholic and drug-induced liver failure.

Response: We are not removing chronic liver disease from the listings, and we do recognize and include hepatitis C, which is a chronic liver disease, under final listings 5.05 and 105.05.

We believe that the many changes and improvements we are making in the final listings and the introductory text in response to these and other comments will make clear that final listings 5.05 and 105.05 apply to all forms of chronic liver disease, including disease caused by the hepatitis B and C viruses. As we have already explained, final listings 5.05 and 105.05 are now broader in scope and more inclusive than the proposed listings were. We did not add a separate listing for chronic hepatitis B or C because individuals with listing-level effects of hepatitis will have the same kinds of findings as those associated with other chronic liver diseases.

In response to these and other comments about chronic viral hepatitis, we are also adding extensive sections to the introductory text to address many of the concerns expressed in the comment letters and at the outreach conference. Final 5.00D4 and 105.00D4, which explain how we evaluate chronic viral hepatitis, are the longest sections in the introductory text. We have provided subsections explaining:

- The nature and course of hepatitis B and C infections;
- Treatment, including the adverse effects of treatment; and
- Extrahepatic manifestations of hepatitis B and C.

With these changes, we believe it will now be very clear that we do consider hepatitis B and C to be medically determinable impairments that could be the basis for a finding of disability. We explain how these impairments can meet the requirements of final listings 5.05 and 105.05, and how they can be disabling in other ways, either by meeting other listings, medically equaling listings, or based on the functional consequences of the impairments as a result of symptoms and the effects of treatment. It should also be clear that we do not intend to restrict the entitlement to disability benefits of individuals who have hepatitis B or C; rather, we intend to include everyone who should qualify under our rules. The new information in final 5.00D4 and 105.00D4 will also ensure that our adjudicators have up-to-date information about hepatitis B and C.

Comment: Some commenters indicated that the debilitating symptoms of hepatitis C virus often begin decades before end-stage liver failure occurs. Some commenters recommended that we include criteria for hepatitis like the criteria in listings 14.08N and 114.08O, for human immunodeficiency virus (HIV). Those listings provide for a finding of disability based on significant documented symptoms or signs with specified functional limitations. The commenters indicated that the symptoms and signs of hepatitis, such as decreased cognitive function, decreased memory acuity, fatigue, weakness, fever, malaise, lethargy, weight loss, abdominal pain, appetite disturbance, mood disturbance, and insomnia, are in many respects the same as the symptoms and signs we include in listings 14.08N and 114.08O. The commenters noted that both HIV and chronic hepatitis B and C are systemic illnesses that encompass a broad spectrum of diseases and potential impairments with many constitutional and systemic signs and symptoms.

One commenter stated that including a listing based on functional limitations would be important for individuals who are homeless and whose functional disabilities may be very profound. The commenter noted that it would be easier to document the functional limitations than the medical conditions because expert medical care may not be available to this group.

A group of physicians who spoke at the outreach meeting commented that they ''struggled with the dilemma of'' how we should evaluate fatigue because they believe it is subjective and difficult to assess and validate. They recommended that the assessment of the validity and impact of fatigue should rest on the judgment of the treating source.

Response: We did not adopt the comments. While we agree that some individuals with hepatitis B and C may be debilitated by symptoms of fatigue and the other symptoms mentioned by the commenters, we believe it would be more appropriate to consider these symptoms on a case-by-case basis at later steps of the sequential evaluation process, based on information obtained from the treating source(s) as well as other medical and non-medical sources concerning the particular effects of the impairments on residual functional capacity or, for children, age-appropriate functioning.

Also, we do not believe we should add a functional listing to the final rules without first proposing it and asking for public comment on the criteria it might contain. Therefore, even though we are not adding such a listing now, we plan to issue an Advance Notice of Proposed Rulemaking inviting public comments on whether we should add a functional listing to the digestive disorders body system and, if so, what functional criteria would be appropriate.

With regard to the comment that we should add a listing based on functional limitations for individuals who are homeless, we do not believe we should add a listing at this time for the reasons stated above; however, we do evaluate functional limitations that result from the symptoms and signs of an impairment when we assess residual functional capacity.

We agree with the physicians who spoke at the outreach meeting that the fatigue associated with hepatitis B and C is often substantial but also difficult to assess and validate. We also agree that treating physicians can provide important information about the validity and impact of fatigue on functioning. In fact, our regulations at §§ 404.1527 and 416.927 require us to consider medical source opinions about the nature and severity of impairments, including opinions about symptoms and their effects on functioning. However, these same rules do not allow us to rely solely on the judgment of the treating physician, as the commenters may have been suggesting. The rules identify factors we must consider in determining whether to accept a treating source's medical opinion, including an opinion about an individual's symptoms. We must also evaluate the symptom of fatigue under §§ 404.1529 and 416.929 of our regulations, which provide a variety of factors that we must consider.

Comment: One commenter suggested that hepatitis C should be included in the hematological body system (7.00 and 107.00) since it is a blood-borne virus.

Response: We did not adopt the comment because hepatitis is primarily a liver disorder and should be evaluated in the digestive disorders body system.

Comment: One commenter stated that only those individuals who suffer from hepatitis C know the extent of their symptoms and only they should make judgments about the appropriate disability criteria for this disease.

Another commenter recommended that we employ doctors who deal with a large number of patients with hepatitis. The commenter further

recommended that we consult with the American Association for the Study of Liver Disease (AASLD) for a list of experts in the field. Another commenter indicated that some doctors who do not deal regularly with an indigent population or those that have retired from active practice may not have expertise in assessing hepatitis B and C. The commenter recommended that community health centers or other public entities should be used as a source of medical expertise.

Response: As we note at the beginning of the comment and response section of this preamble, we reopened the comment period on the NPRM so that we could receive additional input on our rules for evaluating chronic liver disease. In addition to the outreach meeting we conducted in Cambridge, Massachusetts in November of 2004, at which a number of experts presented, we also asked other people with expertise to send us written comments. As a result of these efforts, we received many comments from medical specialists, advocates who specialize in chronic liver disease (including hepatitis B and C), and patients. We adopted many of the comments from these individuals.

We generally agree with the commenters who indicated that it would be better if we used doctors in our program who have expertise in evaluating and treating individuals with hepatitis, or any chronic liver diseases, and we do use such experts whenever possible. We also asked the Institute of Medicine of the National Academies to study the issue of medical expertise in our disability evaluations and to recommend ways in which we can make better use of medical expertise in our case adjudications. They issued their report, *Improving the Social Security Disability Decision Process,* on February 13, 2007.[2] We are now considering their findings and recommendations for future improvements.

Comment: One commenter said that a Veterans Administration (VA) disability rating of 100 percent due to hepatitis C should trigger automatic payment of Social Security disability benefits, as it does for disabled railroad employees. The commenter stated that this would save tax dollars and eliminate inequity between the two Federal programs.

Response: We did not adopt the comment. Under sections 205(b)(1) and 1631(c)(1)(A) of the Act and §§ 404.1504 and 416.904 of our regulations, we are required to make a determination of disability independent of other agencies, such as the VA. Also, the disability standard the VA uses is not the same as our disability standard. However, our regulations do provide that we must consider determinations made by other agencies, including the VA, when we make our determinations and decisions (see §§ 404.1504, 404.1512(b)(5), 416.904, and 416.912(b)(5)).

The reason that a decision awarding disability benefits for the Railroad Retirement Board sometimes applies to Social Security disability benefits is that there is a law that permits this presumption. Also, the determinations of disability that we accept use the same standard that we use for determining disability under our programs; in some cases, we make the determination of disability that the Railroad Retirement Board uses.

Comment: One commenter suggested that hepatitis C should be a category for SSA disability at the point of diagnosis, stating that genotyping and treatment costs are prohibitive. This commenter stated that there was no help for those in the interim between contracting the disease and being near death under the current standards, and those individuals must go without any assistance for years until they meet the criteria in the chronic liver disease listings.

Another commenter noted that the symptoms of hepatitis C virus infection make learning a new, less strenuous trade an unrealistic option if an individual does not become symptomatic until later in life.

Response: While we understand the concern of the first commenter, we do not have the authority to do what the commenter asked. To qualify for Social Security Disability Insurance or Supplemental Security Income benefits, individuals must show that they are disabled under the definition of disability in the Act.

Likewise, with regard to the second comment, we cannot pay disability benefits under the Act to individuals who are not currently disabled but who may become disabled in the future. However, at the fifth step of our sequential evaluation process (described near the end of this preamble) we do consider an individual's age, education, and work experience. At this step, the older an individual becomes, the more likely it is that we will find the individual unable to make an adjustment to other work; that is, the more likely we will find that the individual is disabled.

Comment: One commenter recommended that we include a reference to hepatitis B under recurrent and persistent syndromes because chronic fatigue syndrome (CFS) and depression are common symptoms and these functional limitations are debilitating and prevalent enough that they merit inclusion.

Response: We did not adopt this comment but we did provide guidance on hepatitis B in final 5.00D4b and 105.00D4b. We did not include a reference to CFS in this final rule partly because it is a diagnosis of exclusion; that is, the diagnosis is not made if another physical or mental impairment, such as hepatitis, is present that can account for the symptoms. We explain our policy for evaluating CFS in Social Security Ruling 99–2p, ''Titles II and XVI: Evaluating Cases Involving Chronic Fatigue Syndrome (CFS),'' 83 FR 23380 (April 30, 1999).[3]

Comment: Many commenters stated that individuals undergoing interferon/ribavirin treatment for hepatitis C cannot work as the treatment seriously interferes with physical and mental stamina. One commenter observed that it was unfair to patients and employers to expect those who are undergoing treatment for hepatitis C to work due to the side effects of the treatment. They asked us to use compassion when we make decisions regarding changes in the chronic liver disease criteria. Another commenter stated that disability benefits would be helpful for patients when going through treatment or transplant as the symptoms attack on all fronts.

Response: Partly in response to these comments, we included guidance in final 5.00D4 and 105.00D4 about the types of treatment for hepatitis C, including interferon/ribavirin treatment for adults and children, and the common adverse effects of treatment. However, we cannot automatically grant disability benefits if an individual is undergoing treatment for hepatitis B or C. Everyone reacts differently to the treatment and we must evaluate the disease progression, side effects of treatment, and response to treatment on an individual basis, unless in the future we can identify a diagnostic technique that would allow us to use a conclusive presumption that a case of hepatitis is so severe the individual cannot, as a practical matter, engage in any gainful activity.

Comment: Some commenters suggested that we should include

[2] Institute of Medicine of the National Academies, Committee on Improving the Disability Decision Process. *Improving the Social Security Disability Decision Process.* Washington, DC: The National Academies Press, 2007. The report is available at *http://www.nap.edu/catalog.php?record_id=11859.*

[3] The ruling is also available at *http://www.socialsecurity.gov/OP_Home/rulings/di/01/SSR99=02=di=01.html.*

neuropsychological testing in the evaluation of any person seeking Social Security disability benefits for chronic liver disease, regardless of liver histology, because 50 percent of individuals with chronic hepatitis C experience cognitive impairment and chronic fatigue, even in individuals with mild liver disease.

Response: We did not adopt the comment. Neuropsychological testing is highly specialized, and we generally try to exhaust all other or more direct avenues before we purchase such testing. Also, the testing examines fine areas of brain functioning and not the global functioning that we are generally most interested in for our disability evaluations.

Comment: Several commenters suggested that the medical criteria be kept in line with the National Institutes of Health (NIH) *Consensus Statement on the Management of Hepatitis C* (the Consensus Statement).[4]

Response: With the additional material we added as described above, we believe that these final rules are consistent with the Consensus Statement to the extent appropriate for our disability evaluation criteria under the listings. There is a considerable amount of information in the Consensus Statement that is not specifically relevant to our disability adjudications (for example, discussion of treatment options and recommendations for more education and research) or that goes beyond what is appropriate to include in our listings.

Listings 5.06 and 105.06 Inflammatory Bowel Disease

Comment: We received many comments about IBD. Some commenters were concerned that the listings focused on recurrent intestinal obstruction or fistulae as practically the only criteria for disability due to IBD. The commenters agreed that most individuals with IBD respond to medical or surgical treatment and lead fairly normal lives, but they indicated that there is a subset of individuals who have recurring and persisting disease that is refractory to treatment and makes them unable to work. The commenters suggested that many of these individuals would not be covered by the proposed listings and would face difficulty with their claims.

The commenters indicated that individuals with IBD can be incapacitated by persistent abdominal pain that may be unassociated with either obstruction or fistulae. They also said that profound fatigue due to the underlying inflammatory disease or the resulting and often complex nutritional deficiencies that accompany these disorders may be incapacitating. The commenters mentioned several symptoms and signs that could be refractory to medical and surgical treatment; for example, recurrent obstruction, anemia, fistulae, abscess, or other perineal or intra-abdominal complications. They also noted that recurrent and persisting severe diarrhea, with or without incontinence, makes it impossible for many individuals with IBD to sustain any activity for even modest periods of time. One of the commenters stated that many of the most challenging symptoms of IBD cannot be directly quantified by the usual objective studies, including imaging or laboratory tests, resulting in our excluding relief to many who need and deserve it.

Another commenter stated that we did not sufficiently address recurrent diarrhea and bowel incontinence that do not lead to weight loss or malnutrition. This commenter noted that these conditions may require proximity to a restroom or may interfere with the ability to work in public. The commenter acknowledged that they are ''probably not'' listings issues, but said that there did not appear to be sufficient guidance for disability adjudicators on how to consider these issues.

Two individuals who have IBD and who had filed claims for disability benefits described how profound the disease was for them and expressed concern about any changes we might make that would make it more difficult to qualify. One of these commenters, who has Crohn's disease, described the embarrassment of the disease and the other kinds of illnesses she has had that are associated with the disease and its treatment. The other commenter said that he was against any change in our present regulations that would make it more difficult for a person with IBD to qualify for disability benefits. He said that the proposed changes would cause an added hardship for individuals with IBD.

Response: We adopted most of the comments and completely revised proposed listings 5.06 and 105.06 and the introductory text for IBD. In response to these comments, we added final 5.00E in the introductory text in part A and revised and expanded proposed 105.00F4 (final 105.00E) in part B to provide more detailed guidance for documenting and evaluating IBD in adults and children. We also added criteria in final listings 5.06 and 105.06 to include some of the other manifestations of IBD mentioned by the commenters.

The new sections in the introductory text include most of the examples of symptoms and signs of IBD that the commenters mentioned, as well as others that the commenters did not specifically mention, including a longer list of potential manifestations in other body systems than we included under the prior listings. In addition, we revised proposed listings 5.06 and 105.06 by adding a list of six manifestations in paragraph B of final listing 5.06 and a list of five manifestations in paragraph B of final listing 105.06.

We did not include criteria for manifestations like severe diarrhea or fecal incontinence. We believe that the effect of severe diarrhea is best identified at the listing level by the criteria in 5.06B1 and 105.06B1 (anemia with a hemoglobin of less than 10 g/dL) and 5.06B2 and 105.06B2 (serum albumin of 3.0g/dL or less). We agree that there are other consequences of severe diarrhea or fecal incontinence, such as the necessity to be near a restroom or the difficulty of sustaining activities for even modest amounts of time, that may significantly affect an individual's ability to work or a child's ability to function in an age-appropriate manner. However, we believe these consequences of IBD are more appropriately addressed on an individual case basis when we assess residual functional capacity or functional equivalence.

In considering these comments, we also noted that there were unintentional differences between proposed listings 5.06B and 105.06B, and that we included proposed 105.00F4 (final 105.00E) specifically for children but no corresponding guidance in proposed part A for adults. In making the revisions in the final rules, we determined that, with minor exceptions, there was no need for the information in part A to be different from the information in part B. Therefore, we added final 5.00E to correspond to final 105.00E, and we made a number of editorial changes to 105.00E for consistency between the two sections. Final 5.00E and 105.00E and final listings 5.06 and 105.06 are the same, except for the minor differences necessary to address childhood disability that we have already noted in the explanations of the final rules at the beginning of this preamble.

With regard to the last comments expressing concern that our changes may make it more difficult for individuals with IBD to qualify for disability benefits, we believe that the

[4] *http://consensus.nih.gov/2002/2002HepatitisC2002116PDF.pdf.*

changes we are making in these final rules are an improvement over the proposed rules that address many of the commenters' concerns. Also, the final rules are consistent with advances in medical science and technology, our adjudicative experience, and our goal of appropriately finding all individuals who are unable to perform any gainful activity disabled under the listings.

Comment: One commenter stated that he was ''perplexed'' by the statement in the preamble to the NPRM that ''anemia, when caused by inflammatory bowel disease, is not an appropriate indicator of listing-level severity.'' (See 66 FR at 57013.) The commenter noted that we have long held that chronic anemia with persistent hematocrit below 30 percent is of listing-level severity. The commenter asserted that people with chronic anemia are tired, fatigued, and have poor stamina, and that there are other factors that affect their ability to function.

Another commenter stated that our proposed reasons for changes to the listing were inaccurate. The commenter questioned our statement that ''a gradual reduction in hemoglobin, even to very low levels, is often well tolerated and does not correlate with ability to function.'' (See 66 FR at 57013.) The commenter stated that studies show that quality of life and functional status correlate with hemoglobin levels.

Response: It is true that we have long had listings that are met with anemia demonstrated by hematocrits of 30 percent or less. We also agree that anemia may cause the kinds of symptoms listed. However, listing criteria must represent a level of severity that prevents ''any gainful activity.'' We cannot presume, based only on low hematocrit (or hemoglobin) levels, that the symptoms referred to will be present or sufficiently severe in all cases to determine that an individual is disabled. The body adapts to a gradual lowering of hematocrit (or hemoglobin) levels, therefore there is not a strong correlation between hematocrit levels and the ability to function. We removed a similar criterion from the genitourinary system listings for the same reason. See 70 FR 38582, 38586 (2005).

However, we have included a criterion for anemia with hemoglobin of less than 10 g/dL as one of the criteria of final listings 5.06B and 105.06B. We believe that it is an appropriate criterion when it occurs in conjunction with at least one of the other manifestations of IBD listed in the final rules. We are using hemoglobin (measured in units of g/dL) rather than hematocrit (percent) in assessing the degree of anemia as the former laboratory measurement is more accurate.

Listing 5.08 Weight Loss Due to Any Digestive Disorder

Comment: A commenter suggested that we include guidance that height be measured without shoes in the introductory text to the listings. Another commenter noted that, although we explained in the NPRM how to round inches and centimeters, we did not explain how to round pounds and kilograms.

Response: We adopted the first comment. Because the final listings are based on BMI, we now explain in final 5.00G2a that measurements of both weight and height must be made without shoes.

We did not need to adopt the second comment because we changed the weight loss criteria to BMI measurements and as a consequence removed the proposed rule for rounding. Because of this change, we also did not include the height and weight tables from proposed listing 5.08.

Comment: Two commenters believed that the height and weight tables in the regulations did not reflect the chronicity and severity of disease in individuals with IBD who are routinely treated with corticosteroids. The commenters indicated that corticosteroids lead to substantial salt and water retention and increased fatty tissue accumulation, so that nutritionally depleted patients may have artificially sustained weight. They also noted that it is not uncommon for patients with crippling symptoms, hypoalbuminemia, and nutritional deficiencies to have ''normal'' or increased weight due to the corticosteroids.

Response: We agree with the commenters that individuals with IBD may have ''normal'' weight; however, final listing 5.08 is specifically for individuals with weight loss as a consequence of a digestive disorder. Individuals whose impairments do not meet listing 5.08 may still meet the criteria of another listing. As we explained earlier, we have significantly expanded final listings 5.06 and 105.06 to include criteria for many of the symptoms and signs of IBD. For example, we have included criteria in final 5.06B1 and B8 under which individuals with IBD who are nutritionally depleted but have sustained weight may qualify. Also in response to these comments, we have provided examples in final 5.00E2 and 105.00E2 of signs and laboratory findings that may demonstrate malnutrition in the absence of weight loss, such as edema, anemia, hypoalbuminemia, hypokalemia, hypocalcemia, and hypomagnesemia. If the impairment does not meet or medically equal a listing, we will continue our evaluation through the sequential evaluation process.

Listing 105.08 Malnutrition

Comment: Two commenters suggested that we move the guidelines for what is needed to document malnutrition from proposed 105.00F of the introductory text into listing 105.08 because they were so specific.

Response: We adopted the comments and included three of the proposed examples as criteria in final listing 105.08A. We did not include the example of steatorrhea for reasons we have already explained. Also, as explained earlier, we changed the criteria in final 105.08A1 for anemia to a hemoglobin of less than 10.0 g/dL.

Comment: One commenter suggested that we specify that we use the most current edition when we refer to the CDC chart in listing 105.08 and in the introductory text. This would ensure that the listing criteria continue to reflect the latest guidance.

Response: We adopted the comment. The change appears in final 105.00G2 and in final listings 105.08B1 and B2.

Listings 5.09 and 105.09

Comment: One commenter suggested that as long as an individual is required to take anti-rejection drugs after a transplanted organ, at the very least, medical benefits should continue.

Response: We did not adopt this comment because we do not have the authority to do what the commenter asked. We can only pay benefits to individuals who are under a disability as defined in the Act and our regulations, and Medicare and Medicaid benefits generally depend on continuing entitlement to disability benefits.

Comment: One commenter stated that disability benefits should last for 18 months after a liver transplant because transplants do not remedy the underlying cause of the disease, such as viral hepatitis.

Response: We did not adopt this comment because in our experience 12 months is a sufficient period after which we need to reevaluate each individual's status to see if he or she is still disabled. This is the period we provide for most other transplants. See, for example, listings 3.11 (lung), 4.09 (heart), 6.02 (kidney), 7.17 (aplastic anemia with bone marrow or stem cell transplantation), and 13.05 (lymphoma with bone marrow or stem cell transplantation). Also, we published the

liver transplant listing in 2002 in another notice; these final rules do not make any substantive changes to that rule, only editorial revisions. And as we have already noted, the 1-year rule does not mean that an individual's disability automatically ends 1 year after the transplant. Our rule is only that after 1 year we generally will consider whether the individual is still disabled. Our existing rules also allow our adjudicators to set a later diary date for review of continuing disability if the facts of the case warrant it.

Other Comments

Comment: One commenter did not support our proposal to remove reference listings. The commenter believed that it is easier for our adjudicators to recognize the need to document and evaluate an impairment if it is also included in the listing itself. The commenter also noted that reference listings assure the public and their physicians that a specific impairment has been considered.

Response: We did not adopt the comment. With one exception, all of the reference listings in the part A digestive disorder listings were to listing 5.08, the listing for weight loss. We believe that our adjudicators, the public, and their physicians will easily see that final listing 5.08 is applicable to weight loss due to any digestive disorder. The only exception in part A was for hepatic encephalopathy, which cross-referred to listing 12.02; however, we have now added a listing specifically for hepatic encephalopathy (final listing 5.05F) in the digestive disorders listings. Part B was essentially the same, with most reference listings cross-referring to listing 105.08, and a reference listing for hepatic encephalopathy, which we now list in final listing 105.05F. Prior listing 105.07C also referred to growth impairment listing 100.03. We are removing that reference listing without replacement; however, as we have already noted, we have added references to growth impairment in the introductory text to these listings and we believe that this is sufficient.

We do not agree that the prior reference listings were especially helpful to adjudicators. All individuals who would qualify under any of the provisions of our prior reference listings will continue to qualify under other listings or the rules for medical or functional equivalence for children. Also, because reference listings are redundant, we are removing them from all the body systems as we revise them; therefore, we would be inconsistent if we retained reference listings only in this body system. Our adjudicators are aware that the listings do not include all possible disabling impairments, so they review all of the evidence, including the claimant's allegations and the medical evidence from treating and other medical sources, to identify the impairments they must evaluate.

Comment: One commenter suggested that we include some discussion in the introductory text of how to evaluate digestive impairments for which there is no specific listing, such as peptic ulcer disease and chronic pancreatitis.

Response: We did not add specific information in the introductory text about peptic ulcer disease or chronic pancreatitis because we prefer to include information that is relevant to the application of these listings. However, we do make it clear that we may evaluate digestive disorders that are not specifically named in the introductory text under this body system.

Comment: One commenter asked that we consider the unique health risks and cultural issues that affect Asian Americans and immigrant communities.

Response: We did not adopt the comment. We are not aware of any current medical distinction that supports the suggestion.

Additional Information

What programs do these final rules affect?

These final rules affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these final rules also affect the Medicare and Medicaid programs.

Who can get disability benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act;
- Children of insured workers; and
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured individuals.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How do we define disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above that results in . . .
title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
title XVI	an individual age 18 or older	the inability to do any SGA.
title XVI	an individual under age 18	marked and severe functional limitations.

How do we decide whether you are disabled?

To decide whether you are disabled under the Act, we use a five-step ''sequential evaluation process,'' which we describe in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working, and is the work you are doing substantial gainful activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.

2. Do you have a ''severe'' impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that

you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under SSI. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.924, 416.994, and 416.994a of our regulations. However, all of these processes also include steps at which we consider whether your impairment meets or medically equals one of our listings.

What are the listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI payments based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations, we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How do we use the listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. Part B contains criteria that apply only to individuals who are under age 18. If your impairment does not meet the criteria in part B, we may then use the criteria in part A when those criteria give appropriate consideration to the effects of the impairment(s) in children. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What if you do not have an impairment(s) that meets or medically equals a listing?

We use the listings only to decide that you are disabled or that you are still disabled. We will not deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If you are not working and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the sequential evaluation process that we use to evaluate all disability claims. Likewise, we will not decide that your disability has ended only because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule after we decide that you have experienced medical improvement in your condition(s). See § 416.994a(b)(2).

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

Section 205(a) of the Act and, by reference to section 205(a), section 1631(d)(1) provide that:

> The Commissioner of Social Security shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this title, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under Executive Order 12866, as amended. Thus, they were subject to OMB review.

Our proposed rules met the criteria for an economically significant regulatory action under Executive Order 12866. They were also ''major'' rules under 5 U.S.C. 801ff. For the reasons stated earlier in this preamble, these final rules reflect changes we have made from the proposed rules. Based on these changes, we estimate that these final rules will result in program savings but will not constitute an economically significant regulatory action or ''major'' rules.

We are projecting savings in program expenditures as described below.

Program Savings

1. Title II

We estimate that these final rules would result in reduced program outlays resulting in the following savings (in millions of dollars) to the title II program ($132 million total in a 5-year period beginning in FY 2008).

FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
−$10	−$19	−$27	−$35	−$42	−$132[5]

[5] 5-year total may not be equal to the sum of the annual totals due to rounding.

2. Title XVI

We estimate that these final rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the SSI program ($25 million in a 5-year period beginning in FY 2008).

FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
−$1	−$3	−$5	−$8	−$8	−$25 [6]

[6] Federal SSI payments due on October 1st in fiscal year 2012 are included with payments for the prior fiscal year.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that OMB has approved the information collection requirements contained in Part A, 5.00 and Part B, 105.00 of these final rules. The OMB Control Number for this collection is 0960–0642 expiring March 31, 2008.

(Catalog of Federal Domestic Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Blind, Disability benefits, Old-age, survivors, and disability insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: June 25, 2007.

Michael J. Astrue,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 and subpart I of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

Appendix 1 to Subpart P of Part 404—Listing of Impairments [Amended]

■ 2. Revise item 6 of the introductory text before part A of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

6. Digestive System (5.00 and 105.00): October 19, 2012.

* * * * *

■ 3. Revise section 5.00 in part A of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part A

* * * * *

5.00 DIGESTIVE SYSTEM

A. *What kinds of disorders do we consider in the digestive system?* Disorders of the digestive system include gastrointestinal hemorrhage, hepatic (liver) dysfunction, inflammatory bowel disease, short bowel syndrome, and malnutrition. They may also lead to complications, such as obstruction, or be accompanied by manifestations in other body systems.

B. *What documentation do we need?* We need a record of your medical evidence, including clinical and laboratory findings. The documentation should include appropriate medically acceptable imaging studies and reports of endoscopy, operations, and pathology, as appropriate to each listing, to document the severity and duration of your digestive disorder. Medically acceptable imaging includes, but is not limited to, x-ray imaging, sonography, computerized axial tomography (CAT scan), magnetic resonance imaging (MRI), and radionuclide scans. *Appropriate* means that the technique used is the proper one to support the evaluation and diagnosis of the disorder. The findings required by these listings must occur within the period we are considering in connection with your application or continuing disability review.

C. *How do we consider the effects of treatment?*

1. Digestive disorders frequently respond to medical or surgical treatment; therefore, we generally consider the severity and duration of these disorders within the context of prescribed treatment.

2. We assess the effects of treatment, including medication, therapy, surgery, or any other form of treatment you receive, by determining if there are improvements in the symptoms, signs, and laboratory findings of your digestive disorder. We also assess any side effects of your treatment that may further limit your functioning.

3. To assess the effects of your treatment, we may need information about:

a. The treatment you have been prescribed (for example, the type of medication or therapy, or your use of parenteral (intravenous) nutrition or supplemental enteral nutrition via a gastrostomy);

b. The dosage, method, and frequency of administration;

c. Your response to the treatment;

d. Any adverse effects of such treatment; and

e. The expected duration of the treatment.

4. Because the effects of treatment may be temporary or long-term, in most cases we need information about the impact of your treatment, including its expected duration and side effects, over a sufficient period of time to help us assess its outcome. When adverse effects of treatment contribute to the severity of your impairment(s), we will consider the duration or expected duration of the treatment when we assess the duration of your impairment(s).

5. If you need parenteral (intravenous) nutrition or supplemental enteral nutrition via a gastrostomy to avoid debilitating complications of a digestive disorder, this treatment will not, in itself, indicate that you are unable to do any gainful activity, except under 5.07, short bowel syndrome (see 5.00F).

6. If you have not received ongoing treatment or have not had an ongoing relationship with the medical community despite the existence of a severe impairment(s), we will evaluate the severity and duration of your digestive impairment on the basis of the current medical and other evidence in your case record. If you have not received treatment, you may not be able to show an impairment that meets the criteria of one of the digestive system listings, but your digestive impairment may medically

equal a listing or be disabling based on consideration of your residual functional capacity, age, education, and work experience.

D. *How do we evaluate chronic liver disease?*

1. *General. Chronic liver disease* is characterized by liver cell necrosis, inflammation, or scarring (fibrosis or cirrhosis), due to any cause, that persists for more than 6 months. Chronic liver disease may result in portal hypertension, cholestasis (suppression of bile flow), extrahepatic manifestations, or liver cancer. (We evaluate liver cancer under 13.19.) Significant loss of liver function may be manifested by hemorrhage from varices or portal hypertensive gastropathy, ascites (accumulation of fluid in the abdominal cavity), hydrothorax (ascitic fluid in the chest cavity), or encephalopathy. There can also be progressive deterioration of laboratory findings that are indicative of liver dysfunction. Liver transplantation is the only definitive cure for end stage liver disease (ESLD).

2. *Examples of chronic liver disease* include, but are not limited to, chronic hepatitis, alcoholic liver disease, non-alcoholic steatohepatitis (NASH), primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), autoimmune hepatitis, hemochromatosis, drug-induced liver disease, Wilson's disease, and serum alpha-1 antitrypsin deficiency. Acute hepatic injury is frequently reversible, as in viral, drug-induced, toxin-induced, alcoholic, and ischemic hepatitis. In the absence of evidence of a chronic impairment, episodes of acute liver disease do not meet 5.05.

3. *Manifestations of chronic liver disease.*

a. *Symptoms* may include, but are not limited to, pruritis (itching), fatigue, nausea, loss of appetite, or sleep disturbances. Symptoms of chronic liver disease may have a poor correlation with the severity of liver disease and functional ability.

b. *Signs* may include, but are not limited to, jaundice, enlargement of the liver and spleen, ascites, peripheral edema, and altered mental status.

c. *Laboratory findings* may include, but are not limited to, increased liver enzymes, increased serum total bilirubin, increased ammonia levels, decreased serum albumin, and abnormal coagulation studies, such as increased International Normalized Ratio (INR) or decreased platelet counts. Abnormally low serum albumin or elevated INR levels indicate loss of synthetic liver function, with increased likelihood of cirrhosis and associated complications. However, other abnormal lab tests, such as liver enzymes, serum total bilirubin, or ammonia levels, may have a poor correlation with the severity of liver disease and functional ability. A liver biopsy may demonstrate the degree of liver cell necrosis, inflammation, fibrosis, and cirrhosis. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy. Imaging studies (CAT scan, ultrasound, MRI) may show the size and consistency (fatty liver, scarring) of the liver and document ascites (see 5.00D6).

4. *Chronic viral hepatitis infections.*

a. *General.*

(i) *Chronic viral hepatitis* infections are commonly caused by hepatitis C virus (HCV), and to a lesser extent, hepatitis B virus (HBV). Usually, these are slowly progressive disorders that persist over many years during which the symptoms and signs are typically nonspecific, intermittent, and mild (for example, fatigue, difficulty with concentration, or right upper quadrant pain). Laboratory findings (liver enzymes, imaging studies, liver biopsy pathology) and complications are generally similar in HCV and HBV. The spectrum of these chronic viral hepatitis infections ranges widely and includes an asymptomatic state; insidious disease with mild to moderate symptoms associated with fluctuating liver tests; extrahepatic manifestations; cirrhosis, both compensated and decompensated; ESLD with the need for liver transplantation; and liver cancer. Treatment for chronic viral hepatitis infections varies considerably based on medication tolerance, treatment response, adverse effects of treatment, and duration of the treatment. Comorbid disorders, such as HIV infection, may affect the clinical course of viral hepatitis infection(s) or may alter the response to medical treatment.

(ii) We evaluate all types of chronic viral hepatitis infections under 5.05 or any listing in an affected body system(s). If your impairment(s) does not meet or medically equal a listing, we will consider the effects of your hepatitis when we assess your residual functional capacity.

b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV* infection is diagnosed by the detection of hepatitis B surface antigen (HBsAg) in the blood for at least 6 months. In addition, detection of the hepatitis B envelope antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis and ESLD.

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis and ESLD. Treatment usually includes a combination of interferon injections and oral antiviral agents. Common adverse effects of treatment are the same as noted in 5.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

c. *Chronic hepatitis C virus (HCV) infection.*

(i) *Chronic HCV infection* is diagnosed by the detection of hepatitis C viral RNA in the blood for at least 6 months. Documentation of the therapeutic response to treatment is also monitored by the quantitative assay of serum HCV RNA (''HCV viral load''). Treatment usually includes a combination of interferon injections and oral ribavirin; whether a therapeutic response has occurred is usually assessed after 12 weeks of treatment by checking the HCV viral load. If there has been a substantial reduction in HCV viral load (also known as early viral response, or EVR), this reduction is predictive of a sustained viral response with completion of treatment. Combined therapy is commonly discontinued after 12 weeks when there is no early viral response, since in that circumstance there is little chance of obtaining a sustained viral response (SVR). Otherwise, treatment is usually continued for a total of 48 weeks.

(ii) Combined interferon and ribavirin treatment may have significant adverse effects that may require dosing reduction, planned interruption of treatment, or discontinuation of treatment. Adverse effects may include: Anemia (ribavirin-induced hemolysis), neutropenia, thrombocytopenia, fever, cough, fatigue, myalgia, arthralgia, nausea, loss of appetite, pruritis, and insomnia. Behavioral side effects may also occur. Influenza-like symptoms are generally worse in the first 4 to 6 hours after each interferon injection and during the first weeks of treatment. Adverse effects generally end within a few days after treatment is discontinued.

d. *Extrahepatic manifestations of HBV and HCV.* In addition to their hepatic manifestations, both HBV and HCV may have significant extrahepatic manifestations in a variety of body systems. These include, but are not limited to: Keratoconjunctivitis (sicca syndrome), glomerulonephritis, skin disorders (for example, lichen planus, porphyria cutanea tarda), neuropathy, and immune dysfunction (for example, cryoglobulinemia, Sjögren's syndrome, and vasculitis). The extrahepatic manifestations of HBV and HCV may not correlate with the severity of your hepatic impairment. If your impairment(s) does not meet or medically equal a listing in an affected body system(s), we will consider the effects of your extrahepatic manifestations when we assess your residual functional capacity.

5. *Gastrointestinal hemorrhage* (5.02 and 5.05A). Gastrointestinal hemorrhaging can result in hematemesis (vomiting of blood), melena (tarry stools), or hematochezia (bloody stools). Under 5.02, the required transfusions of at least 2 units of blood must be at least 30 days apart and occur at least three times during a consecutive 6-month period. Under 5.05A, *hemodynamic instability* is diagnosed with signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down) or syncope (fainting). Hemorrhaging that results in hemodynamic instability is potentially life-threatening and therefore requires hospitalization for transfusion and supportive care. Under 5.05A, we require only one hospitalization for transfusion of at least 2 units of blood.

6. *Ascites or hydrothorax* (5.05B) indicates significant loss of liver function due to chronic liver disease. We evaluate ascites or hydrothorax that is not attributable to other causes under 5.05B. The required findings must be present on at least two evaluations at least 60 days apart within a consecutive 6-month period and despite continuing treatment as prescribed.

7. *Spontaneous bacterial peritonitis* (5.05C) is an infectious complication of chronic liver disease. It is diagnosed by ascitic peritoneal fluid that is documented to contain an absolute neutrophil count of at least 250 cells/mm^3. The required finding in 5.05C is satisfied with one evaluation documenting

peritoneal fluid infection. We do not evaluate other causes of peritonitis that are unrelated to chronic liver disease, such as tuberculosis, malignancy, and perforated bowel, under this listing. We evaluate these other causes of peritonitis under the appropriate body system listings.

8. *Hepatorenal syndrome* (5.05D) is defined as functional renal failure associated with chronic liver disease in the absence of underlying kidney pathology. Hepatorenal syndrome is documented by elevation of serum creatinine, marked sodium retention, and oliguria (reduced urine output). The requirements of 5.05D are satisfied with documentation of any one of the three laboratory findings on one evaluation. We do not evaluate known causes of renal dysfunction, such as glomerulonephritis, tubular necrosis, drug-induced renal disease, and renal infections, under this listing. We evaluate these other renal impairments under 6.00ff.

9. *Hepatopulmonary syndrome* (5.05E) is defined as arterial deoxygenation (hypoxemia) that is associated with chronic liver disease due to intrapulmonary arteriovenous shunting and vasodilatation in the absence of other causes of arterial deoxygenation. Clinical manifestations usually include dyspnea, orthodeoxia (increasing hypoxemia with erect position), platypnea (improvement of dyspnea with flat position), cyanosis, and clubbing. The requirements of 5.05E are satisfied with documentation of any one of the findings on one evaluation. In 5.05E1, we require documentation of the altitude of the testing facility because altitude affects the measurement of arterial oxygenation. We will not purchase the specialized studies described in 5.05E2; however, if you have had these studies at a time relevant to your claim, we will make every reasonable effort to obtain the reports for the purpose of establishing whether your impairment meets 5.05E2.

10. *Hepatic encephalopathy* (5.05F).

a. *General.* Hepatic encephalopathy usually indicates severe loss of hepatocellular function. We define hepatic encephalopathy under 5.05F as a recurrent or chronic neuropsychiatric disorder, characterized by abnormal behavior, cognitive dysfunction, altered state of consciousness, and ultimately coma and death. The diagnosis is established by changes in mental status associated with fleeting neurological signs, including ''flapping tremor'' (asterixis), characteristic electroencephalographic (EEG) abnormalities, or abnormal laboratory values that indicate loss of synthetic liver function. We will not purchase the EEG testing described in 5.05F3b; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets 5.05F.

b. *Acute encephalopathy.* We will not evaluate your acute encephalopathy under 5.05F if it results from conditions other than chronic liver disease, such as vascular events and neoplastic diseases. We will evaluate these other causes of acute encephalopathy under the appropriate body system listings.

11. *End stage liver disease (ESLD) documented by scores from the SSA Chronic Liver Disease (SSA CLD) calculation* (5.05G).

a. We will use the SSA CLD score to evaluate your ESLD under 5.05G. We explain how we calculate the SSA CLD score in b. through g. of this section.

b. To calculate the SSA CLD score, we use a formula that includes three laboratory values: Serum total bilirubin (mg/dL), serum creatinine (mg/dL), and International Normalized Ratio (INR). The formula for the SSA CLD score calculation is:

$9.57 \times [\text{Log}_e(\text{serum creatinine mg/dL})]$
$+3.78 \times [\text{Log}_e(\text{serum total bilirubin mg/dL})]$
$+11.2 \times [\text{Log}_e(\text{INR})]$
$+6.43$

c. When we indicate ''Log_e'' in the formula for the SSA CLD score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' (ln) of a numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For example, if an individual has laboratory values of serum creatinine 1.2 mg/dL, serum total bilirubin 2.2 mg/dL, and INR 1.0, we would compute the SSA CLD score as follows:

$9.57 \times [\text{Log}_e(\text{serum creatinine 1.2 mg/dL}) = 0.182]$
$+3.78 \times [\text{Log}_e(\text{serum total bilirubin 2.2 mg/dL}) = 0.788]$
$+11.2 \times [\text{Log}_e(\text{INR 1.0}) = 0]$
$+6.43$

$= 1.74 + 2.98 + 0 + 6.43$
$= 11.15$, which is then rounded to an SSA CLD score of 11.

d. For any SSA CLD score calculation, all of the required laboratory values must have been obtained within 30 days of each other. If there are multiple laboratory values within the 30-day interval for any given laboratory test (serum total bilirubin, serum creatinine, or INR), we will use the highest value for the SSA CLD score calculation. We will round all laboratory values less than 1.0 up to 1.0.

e. Listing 5.05G requires two SSA CLD scores. The laboratory values for the second SSA CLD score calculation must have been obtained at least 60 days after the latest laboratory value for the first SSA CLD score and within the required 6-month period. We will consider the date of each SSA CLD score to be the date of the first laboratory value used for its calculation.

f. If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score.

g. If you have the two SSA CLD scores required by 5.05G, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score.

12. *Liver transplantation* (5.09) may be performed for metabolic liver disease, progressive liver failure, life-threatening complications of liver disease, hepatic malignancy, and acute fulminant hepatitis (viral, drug-induced, or toxin-induced). We will consider you to be disabled for 1 year from the date of the transplantation. Thereafter, we will evaluate your residual impairment(s) by considering the adequacy of post-transplant liver function, the requirement for post-transplant antiviral therapy, the frequency and severity of rejection episodes, comorbid complications, and all adverse treatment effects.

E. *How do we evaluate inflammatory bowel disease (IBD)?*

1. *Inflammatory bowel disease* (5.06) includes, but is not limited to, Crohn's disease and ulcerative colitis. These disorders, while distinct entities, share many clinical, laboratory, and imaging findings, as well as similar treatment regimens. Remissions and exacerbations of variable duration are the hallmark of IBD. Crohn's disease may involve the entire alimentary tract from the mouth to the anus in a segmental, asymmetric fashion. Obstruction, stenosis, fistulization, perineal involvement, and extraintestinal manifestations are common. Crohn's disease is rarely curable and recurrence may be a lifelong problem, even after surgical resection. In contrast, ulcerative colitis only affects the colon. The inflammatory process may be limited to the rectum, extend proximally to include any contiguous segment, or involve the entire colon. Ulcerative colitis may be cured by total colectomy.

2. Symptoms and signs of IBD include diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, palpable abdominal mass (usually inflamed loops of bowel) and perineal disease. You may also have signs or laboratory findings indicating malnutrition, such as weight loss, edema, anemia, hypoalbuminemia, hypokalemia, hypocalcemia, or hypomagnesemia.

3. IBD may be associated with significant extraintestinal manifestations in a variety of body systems. These include, but are not limited to, involvement of the eye (for example, uveitis, episcleritis, iritis); hepatobiliary disease (for example, gallstones, primary sclerosing cholangitis); urologic disease (for example, kidney stones, obstructive hydronephrosis); skin involvement (for example, erythema nodosum, pyoderma gangrenosum); or non-destructive inflammatory arthritis. You may also have associated thromboembolic disorders or vascular disease. These manifestations may not correlate with the severity of your IBD. If your impairment does not meet any of the criteria of 5.06, we will consider the effects of your extraintestinal manifestations in determining whether you have an impairment(s) that meets or medically equals another listing, and we will also consider the effects of your extraintestinal manifestations when we assess your residual functional capacity.

4. Surgical diversion of the intestinal tract, including ileostomy and colostomy, does not preclude any gainful activity if you are able to maintain adequate nutrition and function of the stoma. However, if you are not able to maintain adequate nutrition, we will evaluate your impairment under 5.08.

F. *How do we evaluate short bowel syndrome (SBS)?*

1. *Short bowel syndrome* (5.07) is a disorder that occurs when ischemic vascular insults (for example, volvulus), trauma, or IBD complications require surgical resection of more than one-half of the small intestine, resulting in the loss of intestinal absorptive surface and a state of chronic malnutrition. The management of SBS requires long-term parenteral nutrition via an indwelling central venous catheter (central line); the process is often referred to as *hyperalimentation* or *total parenteral nutrition* (TPN). Individuals with SBS can also feed orally, with variable amounts of nutrients being absorbed through their remaining intestine. Over time, some of these individuals can develop additional intestinal absorptive surface, and may ultimately be able to be weaned off their parenteral nutrition.

2. Your impairment will continue to meet 5.07 as long as you remain dependent on daily parenteral nutrition via a central venous catheter for most of your nutritional requirements. Long-term complications of SBS and parenteral nutrition include central line infections (with or without septicemia), thrombosis, hepatotoxicity, gallstones, and loss of venous access sites. Intestinal transplantation is the only definitive treatment for individuals with SBS who remain chronically dependent on parenteral nutrition.

3. To document SBS, we need a copy of the operative report of intestinal resection, the summary of the hospitalization(s) including: Details of the surgical findings, medically appropriate postoperative imaging studies that reflect the amount of your residual small intestine, or if we cannot get one of these reports, other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

G. *How do we evaluate weight loss due to any digestive disorder?*

1. In addition to the impairments specifically mentioned in these listings, other digestive disorders, such as esophageal stricture, pancreatic insufficiency, and malabsorption, may result in significant weight loss. We evaluate weight loss due to any digestive disorder under 5.08 by using the Body Mass Index (BMI). We also provide a criterion in 5.06B for lesser weight loss resulting from IBD.

2. BMI is the ratio of your weight to the square of your height. Calculation and interpretation of the BMI are independent of gender in adults.

a. We calculate BMI using inches and pounds, meters and kilograms, or centimeters and kilograms. We must have measurements of your weight and height without shoes for these calculations.

b. We calculate BMI using one of the following formulas:

English Formula

$$\text{BMI} = \left(\frac{\text{Weight in Pounds}}{(\text{Height in Inches}) \times (\text{Height in Inches})} \right) \times 703$$

Metric Formula

$$\text{BMI} = \frac{\text{Weight in Kilograms}}{(\text{Height in Meters}) \times (\text{Height in Meters})}$$

Or

$$\text{BMI} = \left(\frac{\text{Weight in Kilograms}}{(\text{Height in Centimeters}) \times (\text{Height in Centimeters})} \right) \times 10,000$$

H. *What do we mean by the phrase ''consider under a disability for 1 year''?* We use the phrase ''consider under a disability for 1 year'' following a specific event in 5.02, 5.05A, and 5.09 to explain how long your impairment can meet the requirements of those particular listings. This phrase does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment continues to meet a listing or is otherwise disabling. For example, if you have received a liver transplant, you may have become disabled before the transplant because of chronic liver disease. Therefore, we do not restrict our determination of the onset of disability to the date of the specified event. We will establish an onset date earlier than the date of the specified event if the evidence in your case record supports such a finding.

I. *How do we evaluate impairments that do not meet one of the digestive disorder listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system. For example, if you have hepatitis B or C and you are depressed, we will evaluate your impairment under 12.04.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In this situation, we will proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether you continue to be disabled, we use the rules in §§ 404.1594, 416.994, and 416.994a as appropriate.

5.01 *Category of Impairments, Digestive System*

5.02 *Gastrointestinal hemorrhaging from any cause, requiring blood transfusion* (with or without hospitalization) of at least 2 units of blood per transfusion, and occurring at least three times during a consecutive 6-month period. The transfusions must be at least 30 days apart within the 6-month period. Consider under a disability for 1 year following the last documented transfusion; thereafter, evaluate the residual impairment(s).

5.03 [Reserved]

5.04 [Reserved]

5.05 *Chronic liver disease,* with:

A. Hemorrhaging from esophageal, gastric, or ectopic varices or from portal hypertensive gastropathy, demonstrated by endoscopy, x-ray, or other appropriate medically acceptable imaging, resulting in hemodynamic instability as defined in 5.00D5, and requiring hospitalization for transfusion of at least 2 units of blood. Consider under a disability for 1 year

following the last documented transfusion; thereafter, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes, despite continuing treatment as prescribed, present on at least two evaluations at least 60 days apart within a consecutive 6-month period. Each evaluation must be documented by:

1. Paracentesis or thoracentesis; or

2. Appropriate medically acceptable imaging or physical examination and one of the following:

a. Serum albumin of 3.0 g/dL or less; or

b. International Normalized Ratio (INR) of at least 1.5.

OR

C. Spontaneous bacterial peritonitis with peritoneal fluid containing an absolute neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome as described in 5.00D8, with one of the following:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 500 mL; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome as described in 5.00D9, with:

1. Arterial oxygenation (P_aO_2) on room air of:

a. 60 mm Hg or less, at test sites less than 3000 feet above sea level, or

b. 55 mm Hg or less, at test sites from 3000 to 6000 feet, or

c. 50 mm Hg or less, at test sites above 6000 feet; or

2. Documentation of intrapulmonary arteriovenous shunting by contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy as described in 5.00D10, with 1 and either 2 or 3:

1. Documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on at least two evaluations at least 60 days apart within a consecutive 6-month period; and

2. History of transjugular intrahepatic portosystemic shunt (TIPS) or any surgical portosystemic shunt: or

3. One of the following occurring on at least two evaluations at least 60 days apart within the same consecutive 6-month period as in F1:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. Electroencephalogram (EEG) demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. International Normalized Ratio (INR) of 1.5 or greater.

OR

G. End stage liver disease with SSA CLD scores of 22 or greater calculated as described in 5.00D11. Consider under a disability from at least the date of the first score.

5.06 *Inflammatory bowel disease (IBD)* documented by endoscopy, biopsy, appropriate medically acceptable imaging, or operative findings with:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by appropriate medically acceptable imaging or in surgery, requiring hospitalization for intestinal decompression or for surgery, and occurring on at least two occasions at least 60 days apart within a consecutive 6-month period;

OR

B. Two of the following despite continuing treatment as prescribed and occurring within the same consecutive 6-month period:

1. Anemia with hemoglobin of less than 10.0 g/dL, present on at least two evaluations at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on at least two evaluations at least 60 days apart; or

3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or

4. Perineal disease with a draining abscess or fistula, with pain that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or

5. Involuntary weight loss of at least 10 percent from baseline, as computed in pounds, kilograms, or BMI, present on at least two evaluations at least 60 days apart; or

6. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter.

5.07 *Short bowel syndrome (SBS),* due to surgical resection of more than one-half of the small intestine, with dependence on daily parenteral nutrition via a central venous catheter (see 5.00F).

5.08 *Weight loss due to any digestive disorder* despite continuing treatment as prescribed, with BMI of less than 17.50 calculated on at least two evaluations at least 60 days apart within a consecutive 6-month period.

5.09 *Liver transplantation.* Consider under a disability for 1 year following the date of transplantation; thereafter, evaluate the residual impairment(s) (see 5.00D12 and 5.00H).

* * * * *

■ 4. Revise listing 6.02C4 in part A of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part A

* * * * *

6.02 * * *

* * * * *

C. * * *

4. Persistent anorexia with weight loss determined by body mass index (BMI) of less than 18.0, calculated on at least two evaluations at least 30 days apart within a consecutive 6-month period (see 5.00G2).

* * * * *

■ 5. Revise listing 12.09G in part A of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part A

* * * * *

12.09 * * *

* * * * *

G. Gastritis. Evaluate under 5.00.

* * * * *

■ 6. Revise section 105.00 in part B of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part B

* * * * *

105.00 DIGESTIVE SYSTEM

A. *What kinds of disorders do we consider in the digestive system?* Disorders of the digestive system include gastrointestinal hemorrhage, hepatic (liver) dysfunction, inflammatory bowel disease, short bowel syndrome, and malnutrition. They may also lead to complications, such as obstruction, or be accompanied by manifestations in other body systems. Congenital abnormalities involving the organs of the gastrointestinal system may interfere with the ability to maintain adequate nutrition, growth, and development.

B. *What documentation do we need?* We need a record of your medical evidence, including clinical and laboratory findings. The documentation should include appropriate medically acceptable imaging studies and reports of endoscopy, operations, and pathology, as appropriate to each listing, to document the severity and duration of your digestive disorder. We may also need assessments of your growth and development. Medically acceptable imaging includes, but is not limited to, x-ray imaging, sonography, computerized axial tomography (CAT scan), magnetic resonance imaging (MRI), and radionuclide scans. *Appropriate* means that the technique used is the proper one to support the evaluation and diagnosis of the disorder. The findings required by these listings must occur within the period we are considering in connection with your application or continuing disability review.

C. *How do we consider the effects of treatment?*

1. Digestive disorders frequently respond to medical or surgical treatment; therefore, we generally consider the severity and duration of these disorders within the context of the prescribed treatment.

2. We assess the effects of treatment, including medication, therapy, surgery, or

any other form of treatment you receive, by determining if there are improvements in the symptoms, signs, and laboratory findings of your digestive disorder. We also assess any side effects of your treatment that may further limit your functioning.

3. To assess the effects of your treatment, we may need information about:

a. The treatment you have been prescribed (for example, the type of medication or therapy, or your use of parenteral (intravenous) nutrition or supplemental enteral nutrition via a gastrostomy);

b. The dosage, method, and frequency of administration;

c. Your response to the treatment;

d. Any adverse effects of such treatment; and

e. The expected duration of the treatment.

4. Because the effects of treatment may be temporary or long-term, in most cases we need information about the impact of your treatment, including its expected duration and side effects, over a sufficient period of time to help us assess its outcome. When adverse effects of treatment contribute to the severity of your impairment(s), we will consider the duration or expected duration of the treatment when we assess the duration of your impairment(s).

5. If you need parenteral (intravenous) nutrition or supplemental enteral nutrition via a gastrostomy to avoid debilitating complications of a digestive disorder, this treatment will not, in itself, indicate that you have marked and severe functional limitations. The exceptions are 105.07, short bowel syndrome, and 105.10, for children who have not attained age 3 and who require supplemental daily enteral feedings via a gastrostomy (see 105.00F and 105.00H).

6. If you have not received ongoing treatment or have not had an ongoing relationship with the medical community despite the existence of a severe impairment(s), we will evaluate the severity and duration of your digestive impairment on the basis of current medical and other evidence in your case record. If you have not received treatment, you may not be able to show an impairment that meets the criteria of one of the digestive system listings, but your digestive impairment may medically equal a listing or functionally equal the listings.

D. *How do we evaluate chronic liver disease?*

1. *General. Chronic liver disease* is characterized by liver cell necrosis, inflammation, or scarring (fibrosis or cirrhosis), due to any cause, that persists for more than 6 months. Chronic liver disease may result in portal hypertension, cholestasis (suppression of bile flow), extrahepatic manifestations, or liver cancer. (We evaluate liver cancer under 113.03.) Significant loss of liver function may be manifested by hemorrhage from varices or portal hypertensive gastropathy, ascites (accumulation of fluid in the abdominal cavity), hydrothorax (ascitic fluid in the chest cavity), or encephalopathy. There can also be progressive deterioration of laboratory findings that are indicative of liver dysfunction. Liver transplantation is the only definitive cure for end stage liver disease (ESLD).

2. *Examples of chronic liver disease* include, but are not limited to, biliary atresia, chronic hepatitis, non-alcoholic steatohepatitis (NASH), primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), autoimmune hepatitis, hemochromatosis, drug-induced liver disease, Wilson's disease, and serum alpha-1 antitrypsin deficiency. Children can also have congenital abnormalities of abdominal organs or inborn metabolic disorders that result in chronic liver disease. Acute hepatic injury is frequently reversible as in viral, drug-induced, toxin-induced, and ischemic hepatitis. In the absence of evidence of a chronic impairment, episodes of acute liver disease do not meet 105.05.

3. *Manifestations of chronic liver disease.*

a. *Symptoms* may include, but are not limited to, pruritis (itching), fatigue, nausea, loss of appetite, or sleep disturbances. Children can also have associated developmental delays or poor school performance. Symptoms of chronic liver disease may have a poor correlation with the severity of liver disease and functional ability.

b. *Signs* may include, but are not limited to, jaundice, enlargement of the liver and spleen, ascites, peripheral edema, and altered mental status.

c. *Laboratory findings* may include, but are not limited to, increased liver enzymes, increased serum total bilirubin, increased ammonia levels, decreased serum albumin, and abnormal coagulation studies, such as increased International Normalized Ratio (INR) or decreased platelet counts. Abnormally low serum albumin or elevated INR levels indicate loss of synthetic liver function, with increased likelihood of cirrhosis and associated complications. However, other abnormal lab tests, such as liver enzymes, serum total bilirubin, or ammonia levels, may have a poor correlation with the severity of liver disease and functional ability. A liver biopsy may demonstrate the degree of liver cell necrosis, inflammation, fibrosis, and cirrhosis. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy. Imaging studies (CAT scan, ultrasound, MRI) may show the size and consistency (fatty liver, scarring) of the liver and document ascites (see 105.00D6).

4. *Chronic viral hepatitis infections.*

a. *General.*

(i) *Chronic viral hepatitis* infections are commonly caused by hepatitis C virus (HCV), and to a lesser extent, hepatitis B virus (HBV). Usually, these are slowly progressive disorders that persist over many years during which the symptoms and signs are typically nonspecific, intermittent, and mild (for example, fatigue, difficulty with concentration, or right upper quadrant pain). Laboratory findings (liver enzymes, imaging studies, liver biopsy pathology) and complications are generally similar in HCV and HBV. The spectrum of these chronic viral hepatitis infections ranges widely and includes an asymptomatic state; insidious disease with mild to moderate symptoms associated with fluctuating liver tests; extrahepatic manifestations; cirrhosis, both compensated and decompensated; ESLD with the need for liver transplantation; and liver cancer. Treatment for chronic viral hepatitis infections varies considerably based on age, medication tolerance, treatment response, adverse effects of treatment, and duration of the treatment. Comorbid disorders, such as HIV infection, may affect the clinical course of viral hepatitis infection(s) or may alter the response to medical treatment.

(ii) We evaluate all types of chronic viral hepatitis infections under 105.05 or any listing in an affected body system(s). If your impairment(s) does not meet or medically equal a listing, we will consider the effects of your hepatitis when we assess whether your impairment(s) functionally equals the listings.

b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV* infection is diagnosed by the detection of hepatitis B surface antigen (HBsAg) in the blood for at least 6 months. In addition, detection of the hepatitis B envelope antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis and ESLD.

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis and ESLD. Treatment usually includes a combination of interferon injections and oral antiviral agents. Common adverse effects of treatment are the same as noted in 105.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

c. *Chronic hepatitis C virus (HCV) infection.*

(i) *Chronic HCV infection* is diagnosed by the detection of hepatitis C viral RNA in the blood for at least 6 months. Documentation of the therapeutic response to treatment is also monitored by the quantitative assay of serum HCV RNA (''HCV viral load''). Treatment usually includes a combination of interferon injections and oral ribavirin; whether a therapeutic response has occurred is usually assessed after 12 weeks of treatment by checking the HCV viral load. If there has been a substantial reduction in HCV viral load (also known as early viral response, or EVR), this reduction is predictive of a sustained viral response with completion of treatment. Combined therapy is commonly discontinued after 12 weeks when there is no early viral response, since in that circumstance there is little chance of obtaining a sustained viral response (SVR). Otherwise, treatment is usually continued for a total of 48 weeks.

(ii) Combined interferon and ribavirin treatment may have significant adverse effects that may require dosing reduction, planned interruption of treatment, or discontinuation of treatment. Adverse effects may include: Anemia (ribavirin-induced hemolysis), neutropenia, thrombocytopenia, fever, cough, fatigue, myalgia, arthralgia, nausea, loss of appetite, pruritis, and insomnia. Behavioral side effects may also occur. Influenza-like symptoms are generally worse in the first 4 to 6 hours after each interferon injection and during the first weeks of treatment. Adverse effects generally end within a few days after treatment is discontinued.

d. *Extrahepatic manifestations of HBV and HCV.* In addition to their hepatic manifestations, both HBV and HCV may have significant extrahepatic manifestations in a variety of body systems. These include, but are not limited to: Keratoconjunctivitis (sicca syndrome), glomerulonephritis, skin disorders (for example, lichen planus, porphyria cutanea tarda), neuropathy, and immune dysfunction (for example, cryoglobulinemia, Sjögren's syndrome, and vasculitis). The extrahepatic manifestations of HBV and HCV may not correlate with the severity of your hepatic impairment. If your impairment(s) does not meet or medically equal a listing in an affected body system(s), we will consider the effects of your extrahepatic manifestations when we determine whether your impairment(s) functionally equals the listings.

5. *Gastrointestinal hemorrhage* (105.02 and 105.05A). Gastrointestinal hemorrhaging can result in hematemesis (vomiting of blood), melena (tarry stools), or hematochezia (bloody stools). Under 105.02, the required transfusions of at least 10 cc of blood/kg of body weight must be at least 30 days apart and occur at least three times during a consecutive 6-month period. Under 105.05A, *hemodynamic instability* is diagnosed with signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down) or syncope (fainting). Hemorrhaging that results in hemodynamic instability is potentially life-threatening and therefore requires hospitalization for transfusion and supportive care. Under 105.05A, we require only one hospitalization for transfusion of at least 10 cc of blood/kg of body weight.

6. *Ascites or hydrothorax* (105.05B) indicates significant loss of liver function due to chronic liver disease. We evaluate ascites or hydrothorax that is not attributable to other causes under 105.05B. The required findings must be present on at least two evaluations at least 60 days apart within a consecutive 6-month period and despite continuing treatment as prescribed.

7. *Spontaneous bacterial peritonitis* (105.05C) is an infectious complication of chronic liver disease. It is diagnosed by ascitic peritoneal fluid that is documented to contain an absolute neutrophil count of at least 250 cells/mm ^{3}. The required finding in 105.05C is satisfied with one evaluation documenting peritoneal fluid infection. We do not evaluate other causes of peritonitis that are unrelated to chronic liver disease, such as tuberculosis, malignancy, and perforated bowel, under this listing. We evaluate these other causes of peritonitis under the appropriate body system listings.

8. *Hepatorenal syndrome* (105.05D) is defined as functional renal failure associated with chronic liver disease in the absence of underlying kidney pathology. Hepatorenal syndrome is documented by elevation of serum creatinine, marked sodium retention, and oliguria (reduced urine output). The requirements of 105.05D are satisfied with documentation of any one of the three laboratory findings on one evaluation. We do not evaluate known causes of renal dysfunction, such as glomerulonephritis, tubular necrosis, drug-induced renal disease, and renal infections, under this listing. We evaluate these other renal impairments under 106.00ff.

9. *Hepatopulmonary syndrome* (105.05E) is defined as arterial deoxygenation (hypoxemia) that is associated with chronic liver disease due to intrapulmonary arteriovenous shunting and vasodilatation, in the absence of other causes of arterial deoxygenation. Clinical manifestations usually include dyspnea, orthodeoxia (increasing hypoxemia with erect position), platypnea (improvement of dyspnea with flat position), cyanosis, and clubbing. The requirements of 105.05E are satisfied with documentation of any one of the findings on one evaluation. In 105.05E1, we require documentation of the altitude of the testing facility because altitude affects the measurement of arterial oxygenation. We will not purchase the specialized studies described in 105.05E2; however, if you have had these studies at a time relevant to your claim, we will make every reasonable effort to obtain the reports for the purpose of establishing whether your impairment meets 105.05E2.

10. *Hepatic encephalopathy* (105.05F).

a. *General.* Hepatic encephalopathy usually indicates severe loss of hepatocellular function. We define hepatic encephalopathy under 105.05F as a recurrent or chronic neuropsychiatric disorder, characterized by abnormal behavior, cognitive dysfunction, altered state of consciousness, and ultimately coma and death. The diagnosis is established by changes in mental status associated with fleeting neurological signs, including ''flapping tremor'' (asterixis), characteristic electroencephalographic (EEG) abnormalities, or abnormal laboratory values that indicate loss of synthetic liver function. We will not purchase the EEG testing described in 105.05F3b. However, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets 105.05F.

b. *Acute encephalopathy.* We will not evaluate your acute encephalopathy under 105.05F if it results from conditions other than chronic liver disease, such as vascular events and neoplastic diseases. We will evaluate these other causes of acute encephalopathy under the appropriate body system listings.

11. *End stage liver disease (ESLD) documented by scores from the SSA Chronic Liver Disease (SSA CLD) calculation (105.05G1) and SSA Chronic Liver Disease-Pediatric (SSA CLD–P) calculation (105.05G2).*

a. *SSA CLD score.*

(i) If you are age 12 or older, we will use the SSA CLD score to evaluate your ESLD under 105.05G1. We explain how we calculate the SSA CLD score in a(ii) through a(vii) of this section.

(ii) To calculate the SSA CLD score, we use a formula that includes three laboratory values: Serum total bilirubin (mg/dL), serum creatinine (mg/dL), and International Normalized Ratio (INR). The formula for the SSA CLD score calculation is:

$$9.57 \times [\text{Log}_e \text{ (serum creatinine mg/dL)}] + 3.78 \times [\text{Log}_e \text{ (serum total bilirubin mg/dL)}] + 11.2 \times [\text{Log}_e \text{ (INR)}] + 6.43$$

(iii) When we indicate ''Log_e'' in the formula for the SSA CLD score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' (ln) of a numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For an example of SSA CLD calculation, see 5.00D11c.

(iv) For any SSA CLD score calculation, all of the required laboratory values must have been obtained within 30 days of each other. If there are multiple laboratory values within the 30-day interval for any given laboratory test (serum total bilirubin, serum creatinine, or INR), we will use the highest value for the SSA CLD score calculation. We will round all laboratory values less than 1.0 up to 1.0.

(v) Listing 105.05G requires two SSA CLD scores. The laboratory values for the second SSA CLD score calculation must have been obtained at least 60 days after the latest laboratory value for the first SSA CLD score and within the required 6-month period. We will consider the date of each SSA CLD score to be the date of the first laboratory value used for its calculation.

(vi) If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score.

(vii) If you have the two SSA CLD scores required by 105.05G1, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score.

b. *SSA CLD–P score.*

(i) If you have not attained age 12, we will use the SSA CLD–P score to evaluate your ESLD under 105.05G2. We explain how we calculate the SSA CLD–P score in b(ii) through b(vii) of this section.

(ii) To calculate the SSA CLD–P score, we use a formula that includes four parameters: Serum total bilirubin (mg/dL), International Normalized Ratio (INR), serum albumin (g/dL), and whether growth failure is occurring. The formula for the SSA CLD–P score calculation is:

$$4.80 \times [\text{Log}_e \text{ (serum total bilirubin mg/dL)}] + 18.57 \times [\text{Log}_e \text{ (INR)}] - 6.87 \times [\text{Log}_e \text{ (serum albumin g/dL)}] + 6.67 \text{ if the child has growth failure } (< -2 \text{ standard deviations for weight or height})$$

(iii) When we indicate ''Log_e'' in the formula for the SSA CLD–P score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' (ln) of a numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For example, if a female child is 4.0 years old, has a current weight of 13.5 kg (10th percentile for age) and height of 92 cm (less than the third percentile for age), and has laboratory values of serum total bilirubin 2.2 mg/dL, INR 1.0, and serum albumin 3.5 g/dL, we will compute the SSA CLD–P score as follows:

$4.80 \times [\text{Log}_e + (\text{serum total bilirubin 2.2 mg/dL}) = 0.788]$
$+18.57 \times [\text{Log}_e (\text{INR 1.0}) = 0]$
$-6.87 \times [\text{Log}_e + (\text{serum albumin 3.5 g/dL}) = 1.253]$
$+6.67$

$= 3.78 + 0 - 8.61 + 6.67$
$= 1.84$, which is then rounded to an SSA CLD–P score of 2

(iv) For any SSA CLD–P score calculation, all of the required laboratory values (serum total bilirubin, INR, or serum albumin) must have been obtained within 30 days of each other. We will not purchase INR values for children who have not attained age 12. If there is no INR value for a child under 12 within the applicable time period, we will use an INR value of 1.1 to calculate the SSA CLD–P score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we will use the highest serum total bilirubin and INR values and the lowest serum albumin value for the SSA CLD–P score calculation. We will round all laboratory values less than 1.0 up to 1.0.

(v) The weight and length/height measurements used for the calculation must be obtained from one evaluation within the same 30-day period as in D11b(iv).

(vi) Listing 105.05G2 requires two SSA CLD–P scores. The laboratory values for the second SSA CLD–P score calculation must have been obtained at least 60 days after the latest laboratory value for the first SSA CLD–P score and within the required 6-month period. We will consider the date of each SSA CLD–P score to be the date of the first laboratory value used for its calculation.

(vii) If you have the two SSA CLD–P scores required by listing 105.05G2, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD–P score.

12. *Extrahepatic biliary atresia (EBA)* (105.05H) usually presents in the first 2 months of life with persistent jaundice. The impairment meets 105.05H if the diagnosis of EBA is confirmed by liver biopsy or intraoperative cholangiogram that shows obliteration of the extrahepatic biliary tree. EBA is usually surgically treated by portoenterostomy (for example, Kasai procedure). If this surgery is not performed in the first months of life or is not completely successful, liver transplantation is indicated. If you have had a liver transplant, we will evaluate your impairment under 105.09.

13. *Liver transplantation* (105.09) may be performed for metabolic liver disease, progressive liver failure, life-threatening complications of liver disease, hepatic malignancy, and acute fulminant hepatitis (viral, drug-induced, or toxin-induced). We will consider you to be disabled for 1 year from the date of the transplantation. Thereafter, we will evaluate your residual impairment(s) by considering the adequacy of post-transplant liver function, the requirement for post-transplant antiviral therapy, the frequency and severity of rejection episodes, comorbid complications, and all adverse treatment effects.

E. *How do we evaluate inflammatory bowel disease (IBD)?*

1. *Inflammatory bowel disease* (105.06) includes, but is not limited to, Crohn's disease and ulcerative colitis. These disorders, while distinct entities, share many clinical, laboratory, and imaging findings, as well as similar treatment regimens. Remissions and exacerbations of variable duration are the hallmark of IBD. Crohn's disease may involve the entire alimentary tract from the mouth to the anus in a segmental, asymmetric fashion. Obstruction, stenosis, fistulization, perineal involvement, and extraintestinal manifestations are common. Crohn's disease is rarely curable and recurrence may be a lifelong problem, even after surgical resection. In contrast, ulcerative colitis only affects the colon. The inflammatory process may be limited to the rectum, extend proximally to include any contiguous segment, or involve the entire colon. Ulcerative colitis may be cured by total colectomy.

2. Symptoms and signs of IBD include diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, palpable abdominal mass (usually inflamed loops of bowel) and perineal disease. You may also have signs or laboratory findings indicating malnutrition, such as weight loss, edema, anemia, hypoalbuminemia, hypokalemia, hypocalcemia, or hypomagnesemia.

3. IBD may be associated with significant extraintestinal manifestations in a variety of body systems. These include, but are not limited to, involvement of the eye (for example, uveitis, episcleritis, iritis); hepatobiliary disease (for example, gallstones, primary sclerosing cholangitis); urologic disease (for example, kidney stones, obstructive hydronephrosis); skin involvement (for example, erythema nodosum, pyoderma gangrenosum); or non-destructive inflammatory arthritis. You may also have associated thromboembolic disorders or vascular disease. These manifestations may not correlate with the severity of your IBD. If your impairment does not meet any of the criteria of 105.06, we will consider the effects of your extraintestinal manifestations in determining whether you have an impairment(s) that meets or medically equals another listing, and we will also consider the effects of your extraintestinal manifestations when we determine whether your impairment(s) functionally equals the listings.

4. Surgical diversion of the intestinal tract, including ileostomy and colostomy, does not very seriously interfere with age-appropriate functioning if you are able to maintain adequate nutrition and function of the stoma. However, if you are not able to maintain adequate nutrition, we will evaluate your impairment under 105.08.

F. *How do we evaluate short bowel syndrome (SBS)?*

1. *Short bowel syndrome* (105.07) is a disorder that occurs when congenital intestinal abnormalities, ischemic vascular insults (for example, necrotizing enterocolitis, volvulus), trauma, or IBD complications require surgical resection of more than one-half of the small intestine, resulting in the loss of intestinal absorptive surface and a state of chronic malnutrition. The management of SBS requires long-term parenteral nutrition via an indwelling central venous catheter (central line); the process is often referred to as *hyperalimentation* or *total parenteral nutrition* (TPN). Children with SBS can also feed orally, with variable amounts of nutrients being absorbed through their remaining intestine. Over time, some of these children can develop additional intestinal absorptive surface, and may ultimately be able to be weaned off their parenteral nutrition.

2. Your impairment will continue to meet 105.07 as long as you remain dependent on daily parenteral nutrition via a central venous catheter for most of your nutritional requirements. Long-term complications of SBS and parenteral nutrition include abnormal growth rates, central line infections (with or without septicemia), thrombosis, hepatotoxicity, gallstones, and loss of venous access sites. Intestinal transplantation is the only definitive treatment for children with SBS who remain chronically dependent on parenteral nutrition.

3. To document SBS, we need a copy of the operative report of intestinal resection, the summary of the hospitalization(s) including: Details of the surgical findings, medically appropriate postoperative imaging studies that reflect the amount of your residual small intestine, or if we cannot get one of these reports, other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

G. *How do we evaluate malnutrition in children?*

1. Many types of digestive disorders can result in malnutrition and growth retardation. To meet the malnutrition criteria in 105.08A, we need documentation of a digestive disorder with associated chronic nutritional deficiency despite prescribed treatment.

2. We evaluate the growth retardation criteria in 105.08B by using the most recent growth charts by the Centers for Disease Control and Prevention (CDC).

a. If you have not attained age 2, we use weight-for-length measurements to assess whether your impairment meets the requirement of 105.08B1. CDC weight-for-length charts are age- and gender-specific.

b. If you are a child age 2 or older, we use BMI-for-age measurements to assess whether your impairment meets the requirement of 105.08B2. BMI is the ratio of your weight to the square of your height. BMI-for-age is plotted on the CDC's gender-specific growth charts.

c. We calculate BMI using inches and pounds, meters and kilograms, or centimeters and kilograms. We must have measurements of your weight and height without shoes for these calculations.

d. We calculate BMI using one of the following formulas:

English Formula

$$\text{BMI} = \left(\frac{\text{Weight in Pounds}}{(\text{Height in Inches}) \times (\text{Height in Inches})} \right) \times 703$$

Metric Formula

$$\text{BMI} = \frac{\text{Weight in Kilograms}}{(\text{Height in Meters}) \times (\text{Height in Meters})}$$

Or

$$\text{BMI} = \left(\frac{\text{Weight in Kilograms}}{(\text{Height in Centimeters}) \times (\text{Height in Centimeters})} \right) \times 10,000$$

H. *How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?*

1. *General.* Infants and young children may have anatomical, neurological, or developmental disorders that interfere with their ability to feed by mouth, resulting in inadequate caloric intake to meet their growth needs. These disorders frequently result in the medical necessity to supplement caloric intake and to bypass the anatomical feeding route of mouth-throat-esophagus into the stomach.

2. Children who have not attained age 3 and who require supplemental daily enteral nutrition via a feeding gastrostomy meet 105.10 regardless of the medical reason for the gastrostomy. Thereafter, we evaluate growth impairment under 100.02, malnutrition under 105.08, or other medical or developmental disorder(s) (including the disorder(s) that necessitated gastrostomy placement) under the appropriate listing(s).

I. *How do we evaluate esophageal stricture or stenosis?* Esophageal stricture or stenosis (narrowing) from congenital atresia (absence or abnormal closure of a tubular body organ) or destructive esophagitis may result in malnutrition or the need for gastrostomy placement, which we evaluate under 105.08 or 105.10. Esophageal stricture or stenosis may also result in complications such as pneumonias due to frequent aspiration, or difficulty in maintaining nutritional status short of listing-level severity. While none of these complications may be of such severity that they would meet the criteria of another listing, the combination of impairments may medically equal the severity of a listing or functionally equal the listings.

J. *What do we mean by the phrase ''consider under a disability for 1 year''?* We use the phrase ''consider under a disability for 1 year'' following a specific event in 105.02, 105.05A, and 105.09 to explain how long your impairment can meet the requirements of those particular listings. This phrase does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment continues to meet a listing or is otherwise disabling. For example, if you have received a liver transplant, you may have become disabled before the transplant because of chronic liver disease. Therefore, we do not restrict our determination of the onset of disability to the date of the specified event. We will establish an onset date earlier than the date of the specified event if the evidence in your case record supports such a finding.

K. *How do we evaluate impairments that do not meet one of the digestive disorder listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system. For example:

a. If you have hepatitis B or C and you are depressed, we will evaluate your impairment under 112.04.

b. If you have multiple congenital abnormalities, we will evaluate your impairment(s) under the criteria in the listings for impairments that affect multiple body systems (110.00) or the criteria of listings in other affected body systems.

c. If you have digestive disorders that interfere with intake, digestion, or absorption of nutrition, and result in a reduction in your rate of growth, and your impairment does not satisfy the criteria in the malnutrition listing (105.08), we will evaluate your impairment under the growth impairment listings (100.00).

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See § 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have an impairment(s) that functionally equals the listings. (See § 416.926a.) When we decide whether you continue to be disabled, we use the rules in § 416.994a.

105.01 *Category of Impairments, Digestive System*

105.02 *Gastrointestinal hemorrhaging from any cause, requiring blood transfusion* (with or without hospitalization) of at least 10 cc of blood/kg of body weight, and occurring at least three times during a consecutive 6-month period. The transfusions must be at least 30 days apart within the 6-month period. Consider under a disability for 1 year following the last documented transfusion; thereafter, evaluate the residual impairment(s).

105.03 [Reserved]

105.04 [Reserved]

105.05 *Chronic liver disease,* with:

A. Hemorrhaging from esophageal, gastric, or ectopic varices or from portal hypertensive gastropathy, demonstrated by endoscopy, x-ray, or other appropriate medically acceptable imaging, resulting in hemodynamic instability as defined in 105.00D5, and requiring hospitalization for transfusion of at least 10 cc of blood/kg of body weight. Consider under a disability for 1 year following the last documented transfusion; thereafter, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes, despite continuing treatment as prescribed, present on at least two evaluations at least 60 days apart within a consecutive 6-month period. Each evaluation must be documented by:

1. Paracentesis or thoracentesis; or

2. Appropriate medically acceptable imaging or physical examination and one of the following:

a. Serum albumin of 3.0 g/dL or less; or

b. International Normalized Ratio (INR) of at least 1.5.

OR

C. Spontaneous bacterial peritonitis with peritoneal fluid containing an absolute neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome as described in 105.00D8, with one of the following:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 1 mL/kg/hr; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome as described in 105.00D9, with:

1. Arterial oxygenation (P_aO_2,) on room air of:

a. 60 mm Hg or less, at test sites less than 3000 feet above sea level, or

b. 55 mm Hg or less, at test sites from 3000 to 6000 feet, or

c. 50 mm Hg or less, at test sites above 6000 feet; or

2. Documentation of intrapulmonary arteriovenous shunting by contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy as described in 105.00D10, with 1 and either 2 or 3:

1. Documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on at least two evaluations at least 60 days apart within a consecutive 6-month period; and

2. History of transjugular intrahepatic portosystemic shunt (TIPS) or any surgical portosystemic shunt; or

3. One of the following occurring on at least two evaluations at least 60 days apart within the same consecutive 6-month period as in F1:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. Electroencephalogram (EEG) demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. International Normalized Ratio (INR) of 1.5 or greater.

OR

G. End Stage Liver Disease, with:

1. For children 12 years of age or older, SSA CLD scores of 22 or greater calculated as described in 105.00D11a. Consider under a disability from at least the date of the first score.

2. For children who have not attained age 12, SSA CLD–P scores of 11 or greater calculated as described in 105.00D11b. Consider under a disability from at least the date of the first score.

OR

H. Extrahepatic biliary atresia as diagnosed on liver biopsy or intraoperative cholangiogram. Consider under a disability for 1 year following the diagnosis; thereafter, evaluate the residual liver function.

105.06 *Inflammatory bowel disease (IBD)* documented by endoscopy, biopsy, appropriate medically acceptable imaging, or operative findings with:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by appropriate medically acceptable imaging or in surgery, requiring hospitalization for intestinal decompression or for surgery, and occurring on at least two occasions at least 60 days apart within a consecutive 6-month period;

OR

B. Two of the following despite continuing treatment as prescribed and occurring within the same consecutive 6-month period:

1. Anemia with hemoglobin less than 10.0 g/dL, present on at least two evaluations at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on at least two evaluations at least 60 days apart; or

3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or

4. Perineal disease with a draining abscess or fistula, with pain that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or

5. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter. (See 105.10 for children who have not attained age 3.)

105.07 *Short bowel syndrome (SBS),* due to surgical resection of more than one-half of the small intestine, with dependence on daily parenteral nutrition via a central venous catheter (see 105.00F).

105.08 *Malnutrition* due to any digestive disorder with:

A. Chronic nutritional deficiency despite continuing treatment as prescribed, present on at least two evaluations at least 60 days apart within a consecutive 6-month period, and documented by one of the following:

1. Anemia with hemoglobin less than 10.0 g/dL; or

2. Serum albumin of 3.0 g/dL or less; or

3. Fat-soluble vitamin, mineral, or trace mineral deficiency;

AND

B. Growth retardation documented by one of the following:

1. For children who have not attained age 2, multiple weight-for-length measurements that are less than the third percentile on the CDC's most recent weight-for-length growth charts, documented at least three times within a consecutive 6-month period; or

2. For children age 2 and older, multiple Body Mass Index (BMI)-for-age measurements that are less than the third percentile on the CDC's most recent BMI-for-age growth charts, documented at least three times within a consecutive 6-month period.

105.09 *Liver transplantation.* Consider under a disability for 1 year following the date of transplantation; thereafter, evaluate the residual impairment(s) (see 105.00D13 and 105.00J).

105.10 *Need for supplemental daily enteral feeding via a gastrostomy* due to any cause, for children who have not attained age 3; thereafter, evaluate the residual impairment(s) (see 105.00H).

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

■ 7. Revise the authority citation for subpart I of part 416 to read as follows:

Authority: Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p) and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

§ 416.924b [Amended]

■ 8. In § 416.924b(b)(3), remove the reference ''§ 416.924a(m)(7) or (8)'' and insert the reference ''§ 416.926a(m)(6) or (7)'' in its place.

§ 416.926a [Amended]

■ 9. In § 416.926a, remove paragraphs (m)(3) and (m)(10) and redesignate paragraphs (m)(4), (m)(5), (m)(6), (m)(7), (m)(8), and (m)(9) as paragraphs (m)(3), (m)(4), (m)(5), (m)(6), (m)(7), and (m)(8).

[FR Doc. E7–20235 Filed 10–18–07; 8:45 am]

BILLING CODE 4191–02–P