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Technical Instructions for Physical or Mental Disorders with Associated Harmful Behaviors and Substance-related Disorders for Civil Surgeons



CDC has updated the 2010 [Technical Instructions for Physical or Mental Disorders with Associated Harmful Behaviors and Substance-related Disorders](#) [PDF – 38 pages] for Civil Surgeons. This is also known as Mental Health Technical Instructions (MH TIs).

The diagnosis of mental disorders and substance-related disorders is made using the current American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. Therefore, the 2010 MH TIs have been modified to reflect the current fifth edition, DSM-5, which was released in the spring of 2013.

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Important changes in the DSM-5 that affect the 2010 MH TIs

- Deletion of the terms “substance abuse,” “substance dependence,” and “substance addiction.”
- Division of substance-related disorders into the following two groups:

1. 1. Substance use disorders
2. 2. Substance-induced disorders

For additional information about the changes please refer to page 5, 6, and 11 of the updated MH TIs PDF.

All civil surgeons should be using the updated MH TIs no later than January 1, 2014.

Preface

Medical screening for physical and mental disorders with associated harmful behaviors and substance-related disorders among persons applying for adjustment of status to permanent resident and other persons required by law to have a medical examination, hereafter referred to as applicants, is an essential component of the immigration-related medical evaluation. Because these conditions are challenging to diagnose and treat, these technical instructions provide a method for recording findings from the medical examination and additional guidance for the civil surgeon in classifying applicants. The new technical instructions use uniform criteria and diagnosis consistent with current medical knowledge and classification connected with legal definitions.

- The required examination includes evaluation of physical and mental disorders with associated harmful behaviors and substance-related disorders. Inadmissibility based on a physical or mental disorder is limited to applicants with associated harmful behavior or potentially harmful behavior.

The Immigration and Nationality Act (INA) provides three grounds of inadmissibility related to substance addiction or abuse, or physical or mental disorders that affect behavior. They are -

- Current physical or mental disorder with associated harmful behavior.
- Past physical or mental disorder with associated harmful behavior if the harmful behavior is likely to recur or to lead to other harmful behavior in the future.
- Drug (substance) abuse or addiction (medically called dependence). Dependence on or abuse of any of the substances listed in Section 202 of the Controlled Substances Act (Appendix C). (The term addiction corresponds with the medical term dependence).

The instructions in this document supersede all previous Technical Instructions, Updates to the Technical Instructions, memoranda and letters to civil surgeons relating to substance abuse or addiction and mental or physical disorders with associated harmful behavior (whether past or present). These new instructions are to be followed when determining whether an applicant is afflicted with physical and mental disorders with associated harmful behaviors and substance-related disorders among all applicants.

For any questions about these Technical Instructions, please contact the Immigrant, Refugee,

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and Migrant Health Branch of the Division of Global Migration and Quarantine (DGMQ),
Centers for Disease Control and Prevention (CDC), at cdcQAP@cdc.gov or 404-498-1600.
These Technical Instructions and other information pertinent to them and the medical
examination for applicants for U.S. immigration can be found online at
<https://www.cdc.gov/immigrantrefugeehealth/exams/ti/civil/technical-instructions-civil-surgeons.html>.

Role of the Civil Surgeon

The purpose of the immigration examination is to identify health-related conditions that render an applicant *inadmissible*, and also to identify and inform the applicant of conditions possibly needing follow-up care.

As part of the medical evaluation and physical examination of the applicant, the civil surgeon will carry out or obtain a mental health evaluation –

- To identify and diagnose any physical or mental disorder (including alcohol-related disorders).
- To identify any harmful behavior associated with a disorder.
- To identify the use of drugs, other than those required for medical reasons, and diagnose any substance-related disorder.
- To determine the remission status of any disorder previously diagnosed.
- To determine the likelihood of recurrence of harmful behaviors associated with a physical or mental disorder.

For most applicants, the civil surgeon's examination will require only one appointment. However, for some applicants multiple appointments or specialist consultations may be required to make an accurate diagnosis of whether the applicant is afflicted with a Class A or Class B condition as it relates to physical or mental disorders with associated harmful behavior or substance abuse and addiction (dependence).

Key Concepts

A harmful behavior is defined as an action associated with a mental or physical disorder that is or has caused –

- Serious psychological or physical injury to the applicant or to others (e.g., a suicide attempt or pedophilia)
- A serious threat to health or safety (e.g., driving while intoxicated or verbally threatening to kill someone)
- Major property damage.

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An applicant who has exhibited harmful behavior not associated with a specific mental or physical disorder is not considered inadmissible under health-related grounds, but may be inadmissible under criminal grounds as determined by DHS/USCIS.

The Diagnostic and Statistical Manual of Mental Disorders' (DSM) diagnosis for substance-related disorders is used in this examination to determine "drug abuse" and "drug addiction" which are listed as a medical ground of inadmissibility in the Immigration and Nationality Act.

Alcohol dependence or abuse alone is not considered a Class A condition. It is considered the same as any other mental disorder, and requires associated harmful behavior to be classified as a medically inadmissible condition.

Physical Disorder

A physical disorder is a clinically diagnosed medical condition where the focus of attention is physical manifestations. Only physical conditions that are included in the current version of the World Health Organization's *Manual of the International Classification of Diseases (ICD)* will be considered for the purpose of this examination.

Mental Disorder

Mental disorders are health conditions that are characterized by alterations in thinking, mood, or behavior (or some combination thereof). The current version of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM)* is an authoritative source on the classification of mental disorders and should be considered for the purpose of this examination.

"V" Coded Condition

"V" coded conditions listed in the DSM are not diagnoses, but are used in clinical practice settings when the focus of clinical attention is on a behavior that is not due to a mental disorder. Because these "V" conditions are not mental disorders, they cannot be used in determining if a person has an *inadmissible* (Class A) health-related condition, regardless of whether there is an associated harmful behavior. However, behaviors associated with "V" coded conditions might require treatment.

Harmful Behavior

The civil surgeon is to identify any harmful behavior that is associated with an applicant's physical or mental disorder.

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Only harmful behavior that is associated with a physical or mental disorder is relevant for the classification of U.S. medical eligibility; neither harmful behavior by itself nor the physical or mental disorder by itself makes an applicant medically inadmissible. People can have multiple harmful behaviors that are not associated with a physical or mental disorder. Repetitive antisocial activities and harmful acts may warrant evaluation for personality disorders according to DSM criteria, and eventually provide a basis for the conclusion of inadmissibility. Because of the complexity of this issue, the civil surgeon might feel that a more specialized psychiatric examination is indicated. (Table 4)

Substance-Related Disorders

To establish any substance-related disorder diagnosis, the examining physician must document the pattern of use and behavioral, physical, and psychological effects associated with the use or cessation of use of that substance. Diagnoses of substance-related disorders are to be made in accordance with existing medical standards as determined by the current edition of the DSM. In the current DSM, substance-related disorders are divided into the following two groups:

1. Substance use disorders
2. Substance-induced disorders

For purposes of this evaluation, substances are divided into two groups, controlled substances and non-controlled substances. Controlled substances are any substance listed in Schedules I through V of Section 202 of the Controlled Substances Act. (See Appendix C.) Non-controlled substances include alcohol and all other substances.

Substances used for clinical care in medical practice are not prohibited. Prescription drugs taken in accordance with a prescription do not amount to a substance use disorder. However, abuse of prescription drugs could be a substance-related disorder. This requires a full evaluation by the examining physician to determine whether illicit drugs are being used, because use of illicit drugs is a risk factor for the misuse of prescribed, controlled substances.

Substance Use Disorders

The essential feature of a substance use disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems.

The DSM criteria for substance use disorders fit within overall groupings of *impaired control, social impairment, risky use, and pharmacological criteria*. Pharmacological criteria include tolerance and withdrawal.

Drug (substance) abuse or addiction (medically called dependence) is listed as a medical ground of inadmissibility by the Immigration and Nationality Act (INA). An applicant will be barred from admission if he or she

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- Uses a controlled substance

AND

- Meets DSM criteria for a substance use disorder.

The DSM uses the following criteria to determine the severity of a substance use disorder:

- The presence of 2-3 symptoms (this suggests a mild substance use disorder)
- The presence of 4-5 symptoms (this suggests a moderate substance use disorder)
- The presence of 6 or more symptoms (this suggests a severe substance use disorder)

If an applicant's substance use meets criteria for either a mild, moderate, or severe substance use disorder, and involves a controlled substance, the applicant is considered Class A for drug abuse/addiction.

If an applicant's substance use meets the criteria for either a mild, moderate, or severe substance use disorder but involves a non-controlled substance, the civil surgeon should determine whether harmful behavior is present or if there is a history of harmful behavior that is judged likely to recur. If harmful behavior is present or is judged likely to recur, then the applicant is considered Class A for a physical or mental disorder. If the applicant does not currently have harmful behavior or does not have a history of harmful behavior judged likely to recur, the applicant is considered Class B for a physical or mental disorder.

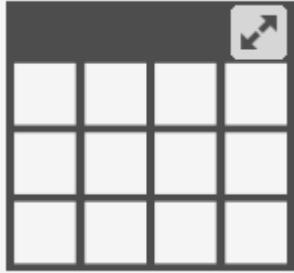
Substance-Induced Disorders

In addition to substance use disorders, the DSM has a separate category called substance-induced disorders. The DSM list of substance-induced disorders includes but is not limited to intoxication, withdrawal, and other substance/medication-induced mental disorders (psychotic disorders, bipolar and related disorders, depressive disorders, anxiety disorders, obsessive-compulsive and related disorders, sleep disorders, sexual dysfunctions, delirium, and neurocognitive disorders/substance-induced psychotic disorder, and substance-induced depressive disorder).

If an applicant's substance use meets the DSM criteria for a substance-induced disorder, and involves the use of a controlled substance, the applicant is considered Class A for drug abuse/addiction.

If an applicant's substance use meets the criteria for a substance-induced disorder but involves a non-controlled substance, the civil surgeon should determine whether harmful behavior is present or if there is a history of harmful behavior that is judged likely to recur. If harmful behavior is present or is judged likely to recur, then the applicant is considered Class A for a physical or mental disorder. If the applicant does not currently have harmful behavior or a history of harmful behavior judged likely to recur, the applicant is considered Class B for a physical or mental disorder.

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Class A and Class B Medical Conditions

Class A medical conditions are inadmissible conditions and include an applicant who is determined to have –

- A current physical or mental disorder with associated harmful behavior
- A past physical or mental disorder with associated harmful behavior if the harmful behavior is likely to recur or to lead to other harmful behavior in the future
- Drug (substance) abuse or addiction (dependence)

Class B medical conditions are not inadmissible medical conditions and include any applicant who is determined to have a physical or mental abnormality, disease, or disability serious in degree or nature amounting to a substantial departure from well-being.

Mental Health Examination

Observation alone is not sufficient to assess an applicant.

Random screening for drugs is not part of the routine medical evaluation of applicants for U.S. admission.

If the civil surgeon is unable to determine whether an applicant has a diagnosis of a physical or mental disorder, or substance abuse or dependence for a substance listed in Section 202 of the Controlled Substances Act, diagnosis and classification may be deferred in order to obtain additional medical evidence.

Record DSM diagnoses for mental disorders and substance-related disorders on the I-693 Form under Part 2, in the Remarks for Number 3 and Number 4.

The civil surgeon can recognize that an applicant with a physical or mental disorder might have an associated harmful behavior during any point of the examination.

- While taking the medical history of a mental disorder,

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- While taking history of harmful behavior, or
- While observing for current abnormal behavior during the physical examination.

Medical History

The civil surgeon should begin by asking questions about the past medical history of the applicant. To fully investigate the applicant's past medical history, the civil surgeon, when possible, should –

- Obtain other relevant records, such as police, military, school, and employment, that might provide a history of harmful behavior associated with physical or mental disorders.
- Ask about mental disorders in the family and, when appropriate, about signs of mental problems or odd behaviors.
- Ask about any use of drugs and medicines.
- Ask about harmful behaviors.

When a civil surgeon defers diagnosis and classification, the civil surgeon should explain to the applicant what the civil surgeon would like to see during the next 3-6 months (in order to classify the applicant) to show abstinence (see Figure 2). This may include but is not limited to requiring clinical reports from health care professionals for applicants with possible substance-related disorders to demonstrate participation in a drug treatment program. For applicants with deferred diagnosis and classification, the civil surgeon should consider documenting in a statement signed by the applicant the information he or she is providing to the applicant; the statement should specify what is required during the next 3 to 6 months (see Figure 2) to show abstinence.

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Psychiatric Evaluation

The civil surgeon should conduct an activities assessment and mental status examination that assesses, at a minimum –

- orientation,
- mood and affect,
- speech and language,
- anxiety,
- thought processes and content, and
- behavior.

The civil surgeon may estimate the degree of cognitive impairment in dementia or mental retardation by assessing the applicant's (1) level of knowledge, and (2) ability to carry out functions of daily living (e.g., learning, communication, and routine activities).

Any available reports of cognitive, development, or intelligence testing, or neuropsychological testing in the medical record are welcome and may be included with the civil surgeon's report.

However, the civil surgeon is not asked to routinely send applicants for additional psychological tests.

Under most circumstances, the civil surgeon or consultant will not need to provide additional psychological or neuropsychological testing. Use of projective instruments, such as Rorschach test, may not be useful given the added administrative burden involved. No psychological or neuropsychological testing is a substitute for the civil surgeon's or consultant's history and examination of the applicant. However, for certain cases, these tests may aid in making a diagnosis.

Laboratory Testing

Random screening for drugs is not part of the routine medical examination for applicants for U.S. admission. The civil surgeon needs to evaluate the applicant's history, behavior and physical appearance when determining if drug screening should be performed.

Whole populations of applicants should not routinely be subject to random laboratory screening. The civil surgeon should make an individual decision based on the indications for drug screening (see Table 1).

Laboratory testing to identify underlining medical conditions that might be causing psychiatric manifestations may be necessary before making any mental disorder diagnoses. However, specialized laboratory testing, such as dexamethasone suppression tests or challenge administration of various pharmaceuticals, is usually not indicated in the diagnosis of applicants.

Other possible uses of laboratory support depend on the availability of such laboratory services and the clinical judgment of the civil surgeon as to their usefulness in classification of the individual applicant. For example, therapeutic levels of prescribed anticonvulsant medications, antipsychotic medications, or other medicines used in psychiatry (such as lithium levels) might be of value to the civil surgeon in –

- Determining the applicant's adherence to a prescribed course of treatment.
- Possibly changing or adjusting the applicant's medications, and therefore contributing to remission of illness and reduction of associated harmful behavior.

Random screening for drugs on short notice to the applicant can provide additional evidence to aid in diagnosis and classification. For example, the civil surgeon might request that three random screenings for drugs within a 3- to 6-month period be done with only 24- to 48-hour notification to the applicant. The period of advance notification should be the minimum practical time for the applicant to arrive at the screening facility, preferably 24 or 48 hours after notification.

It is the civil surgeon's responsibility to know the reliability and validity of the laboratory tests

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and laboratory methods used during the medical evaluation. All drug testing is to be done by using materials licensed by the U.S. Food and Drug Administration or by the equivalent licensing office in other countries. Rapid testing or semi-quantitative testing may be used for the screening test; however, gas chromatography/mass spectrometry (GC/MS), performed at a reference laboratory, needs to be used as the confirmatory test. Positive and negative controls must be used with any testing and only test kits that are for medical diagnosis and treatment must be used. Forensic testing is minimally regulated and will be labeled "not for medical diagnosis and treatment" and, therefore, should not be used because it is not sensitive enough for medical purposes.

Mental or Physical Disorders With Associated Harmful Behavior

Only mental or physical disorders during which the applicant engages in or has engaged in harmful behavior that is associated with (due to) the mental or physical disorder will make an applicant inadmissible. As previously stated, no diagnosis of a mental or physical disorder by itself provides a basis for inadmissibility. There must also be a determination made regarding current harmful behavior or a history of harmful behavior, associated with or caused by the disorder, and the likelihood of associated harmful behavior to recur, in order to provide basis for inadmissibility.

Thus, when evaluating an applicant for possible mental disorders, it is vital to assess for the likelihood of harmful behavior. Because there are mental disorders that are commonly associated with harmful behavior, it may be helpful to first look for the harmful behavior when assessing an applicant for a possible mental disorder. (See Figure 1)

Mental disorders most frequently associated with harmful behavior include –

- major depression,
- bipolar disorder,
- schizophrenia, and
- mental retardation.

These disorders occur within broader categories of disorders that can be grouped as –

- Mood disorders that include major depression and bipolar disorders and can be associated with high rates of suicide and aggression.
- Anxiety disorders that include post-traumatic stress disorder, panic disorders, phobias, and anxiety disorders and can be associated with harmful behavior.
- Personality disorders that include antisocial, paranoid, and borderline personality disorders and can be associated with impulsive acts of violence.
- Sexual disorders that include paraphilic disorders.
- Schizophrenia and other psychotic disorders that can be associated with delusions, paranoia, suicide, and aggressive acts.

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- Disorders usually first diagnosed in childhood that include mental retardation and conduct disorder and are often associated with harmful behaviors. In addition, other cognitive disorders, such as dementia, can be associated with harmful behaviors.
- Substance-related disorders that include substance dependence or abuse. For specific substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C), no associated harmful behavior is required for the applicant to have a medically inadmissible condition based on substance abuse/dependence (please see above for the determination of substance abuse/dependence). The civil surgeon is reminded that for substances not listed in Schedule I-V (such as alcohol), that abuse or dependence is evaluated as a mental disorder and determination of associated harmful behavior is required for applicant to have a medically inadmissible condition. With alcohol dependence or abuse there is often associated harmful behavior during periods of intoxication and withdrawal.

Physical Disorder

Physical disorders are rarely associated with harmful behavior. It may happen in delirious or confused states due to metabolic disturbances, hypoglycemia; and some psychomotor epilepsies and in the aftermath of generalized seizure disorders and various forms of seizure disorders. When evaluating an applicant for a physical disorder with associated harmful behavior, the civil surgeon should diagnosis physical disorders according to the conventions used in the current edition of the ICD published by the World Health Organization.

Current Harmful Behavior

If the applicant is currently engaging in harmful behavior, that is, harmful behavior (see definition above) that has continuously occurred and seems ongoing, the civil surgeon must evaluate whether the actions may be indicative of a mental disorder.

Future Harmful Behavior

If the applicant presently is or in the past has engaged in harmful behavior associated with a physical or mental disorder, the civil surgeon must evaluate whether the harmful behavior is likely to recur. Many factors enter into this determination of classification, and the decision requires clinical judgment. At a minimum, the underlying physical or mental disorder must be either in remission or reliably controlled by medication or other effective treatment.

As a general guideline, when a mental or physical disorder has a favorable prognosis and is in remission or under control but there was associated harmful behavior, if it has been 12 months since the harmful behavior occurred, the harmful behavior is less likely to recur (see Table 3).

Remission

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The current version of the DSM defines sustained, full remission as a period of at least 12 months during which no substance use or mental disorder-associated behaviors have occurred. These new technical instructions reflect the current medical knowledge and standards of the DSM. The panel physician and his or her consultant must use their clinical judgment in determining if 12 months is an acceptable period of time for the individual applicant to demonstrate sustained, full remission. This time period must be based on the reliability of the evidence provided, such as clinical reports of participation in a program, such as a drug treatment program.

Remission must also be considered in two contexts: (1) general mental disorders and (2) substance-related disorders.

For general mental disorders, the determination of remission must be made based on the assessment of associated harmful behavior, either current or history of judged likely to recur and DSM criteria. This includes substance-related disorders for those substances, including alcohol, not listed in Schedules I through V of Section 202 of the Controlled Substances Act.

For substance-related disorders for those substances listed in Schedule I through V of Section 202 of the Controlled Substances Act, the determination of remission must be made based on applicant's substance use and DSM criteria.

The practical significance for diagnosis of remission is that applicants who are or have been determined to be Class A for abuse or addiction for those substances listed in Schedule I through V of Section 202 of the Controlled Substance Act are not eligible for a waiver and must complete the time period for sustained, full remission before reapplying for admission.

The civil surgeon must exercise judgment in reevaluating applicants with a previous Class A determination who are reapplying for admission. If the disorder is in the past, the decision is whether to classify the applicant as Class A or B. If the disorder is current, the decision becomes whether the applicant is still Class A or is in a period of remission sufficient to lend confidence that remission is sustained and full. In other words, if the applicant is currently in remission, what is the likelihood that the remission will be sustained? (See Table 2)

Sexually Dangerous People

Not all sexually dangerous people have behaviors attributable to a psychiatric or general medical disorder. For instance, rapist is not a psychiatric diagnosis. However, people diagnosed with paraphilic disorders might commit rape when their intense sexual fantasy, urge, or fetish is enacted with a child or other non-consenting person. People who have harmful behaviors associated with sexual acts, whether reported as a criminal act or psychiatric disorder, have been shown not to benefit reliably from treatment programs. Documented or acknowledged episodes of paraphilia might represent only a fraction of the sexually dangerous person's history of related harmful behaviors. Given the pattern of recurring harmful behaviors in paraphilia and the high

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relapse rate of sexual offenders, applicants with a history of harmful behavior associated with sexual acts are almost always likely to have a recurrence of harmful behavior and therefore remain medically classifiable as a Class A mental disorder with associated harmful behavior.

Referring the Applicant to a Specialist for Psychiatric Examination

After reviewing the applicant's available records (such as medical, psychiatric, police, military, school, and employment) and performing mental status and physical examinations (including an Activities Assessment and Mental Status Assessment), the civil surgeon may feel that a more specialized psychiatric examination is indicated. (See Table 4)

If an applicant has been referred to a specialist for psychiatric evaluation and the civil surgeon still needs guidance and assistance in determining the diagnosis and classification of a Class A or Class B or No Class A or Class B condition, DGMQ may be consulted to provide additional assistance.

A copy of all the pertinent medical information may be faxed to 404-639-4441, sent via secure files to cdcQAP@cdc.gov, or mailed to the following address:

Quality Assessment Program
Division of Global Migration and Quarantine
Centers for Disease Control and Prevention, Mailstop E-03
1600 Clifton Road, Atlanta, Georgia 30333, USA

Mental Health Screening Results

The mental health screening is complete when all required aspects of the medical examination have been finalized, including if indicated, the report of the specialist and laboratory test results. At this time, the civil surgeon should be able to assign to the applicant a classification regarding a physical or mental disorder or substance-related disorder.

For physical or mental disorders with associated harmful behavior (past and present), or substance-related disorders, the civil surgeon should use the below outlined screening results to classify applicants as Class A or Class B.

Pertinent information relating to physical or mental disorders, and substance related disorders should be indicated on the I-693.

Screening Results

- Applicants without findings suggestive of mental or physical disorders, or substance abuse or addiction. (No Class A or B Physical or Mental Disorder, No Class A or B Drug Abuse/Addiction).

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- Applicants with physical and mental disorders that affect behavior but no associated harmful behavior, and who do not have substance abuse or addiction. (No Class A or B Physical or Mental Disorder, No Class A or B Drug Abuse/Addiction).
- Applicants with "addiction" (dependence) or abuse of any of the substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C) with or without associated harmful behavior. (Class A Substance (Drug) Use, Listed in Section 202 of the Controlled Substance Act.). Applicants may not apply for a waiver of eligibility.
- Applicants with a diagnosis of a current physical or mental disorder (including other substance-related disorders such as alcohol-related disorders) with associated harmful behavior. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with a history of a physical or mental disorder (including other substance-related disorders, such as alcohol-related disorders) with associated harmful behavior and whose harmful behavior is likely to recur or lead to other harmful behavior. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with a history of alcohol-related arrests or convictions (e.g., driving under the influence [DUI]) who currently continues to drink alcohol and who meets DSM criteria for alcohol abuse. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with single alcohol related arrest or conviction within the last five years, or two or more arrests or convictions within the last ten years should be evaluated for alcohol abuse (mental health classification pending).
- Applicants who meet DSM criteria for mood disorders or schizophrenic disorders with associated harmful behavior, either current or judged likely to recur. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with sustained, full remission of "addiction" (dependence) or abuse of any of the specific substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C) may be assigned a Class B, Prior Substance (Drug) Use in Remission.
- Applicants with a history of a diagnosable physical or mental disorder (including other substance-related disorders, such as alcohol-related disorders) with associated harmful behavior when the harmful behavior is judged unlikely to recur or lead to other harmful behavior may be assigned a Class B, Physical/Mental Disorder without Associated Harmful Behavior.
- Applicants who are diagnosed with a physical disorder that affects behavior or a mental disorder (including substance-related disorders) that is significant enough to require clinical attention but who have had no associated harmful behavior (such as those with seizure disorders, mental retardation, or schizophrenia without associated harmful behavior) may be assigned a Class B, Physical/Mental Disorder without Associated Harmful Behavior.
- Applicants with history of alcohol related arrests or convictions that currently meets DSM criteria for full, sustained remission, may be assigned a Class B Physical/Mental Disorder

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Without Associated Harmful Behavior.

- Applicant with a current or past history of mood disorders or schizophrenic disorders without associated harmful behavior may be assigned a Class B Physical/Mental Disorder Without Associated Harmful Behavior.
- Applicants with history of non-medical use of specific categories of substances that currently meets DSM criteria for full, sustained remission may be assigned a Class B, Prior Substance (Drug) Use in Remission.

Waivers

A provision allows applicants diagnosed with a mental or physical disorder with associated harmful behavior to apply for a Class A waiver.

Most applicants diagnosed with substance abuse or addiction are not eligible to apply for a Class A waiver.

Applicants diagnosed with substance abuse or addiction who are subsequently found to be in remission and reclassified as Class B do not need to apply for a waiver.

A provision allows applicants with a Class A physical disorder or mental disorder with associated harmful behavior to petition for a Class A waiver. Form I-601 or I-602 (for immigrants or refugees, respectively) must be completed. These waivers are submitted to the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) on an individual basis. DGMQ also reviews the waivers and supporting medical examination to provide an opinion regarding the case to the requesting entity (DOS or DHS, USCIS). DGMQ's review of the waiver and supporting medical examination documentation is to ensure that the applicant has been classified properly and that an appropriate U.S. health care provider is identified for the applicant. DHS, USCIS has the final authority to adjudicate the waiver request.

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Most applicants diagnosed with substance abuse or addiction (dependence) for specific substance categories based on current DSM criteria and classified as Class A are not eligible for a waiver.

Applicants who were previously diagnosed as Class A for substance abuse or addiction and subsequently found to be in remission and reclassified as Class B do not require a waiver.

Mental Health and Substance Abuse/Addiction Classifications and Descriptions

Applicants may be assigned one or more mental or physical disorders with associated

harmful behavior and substance-related disorders classification on the I-693 Form.

The physical and mental disorders with associated harmful behaviors and substance related disorders are listed below. Applicants may have more than one classification. However, applicants cannot be classified as both Class A and Class B for the same physical or mental disorder, or substance related disorder.

No Class A or Class B Classification

- Applicants with no diagnosis of physical or mental disorder, or substance related disorder.
- Applicants diagnosed with physical and mental disorders based on current DSM criteria that affect behavior but do not meet criteria for Class A or Class B.

Class A Physical or Mental Disorder with Associated Harmful Behavior

- Applicants diagnosed with current physical or mental disorder based on current DSM criteria with associated harmful behavior.
- Applicants diagnosed with history of physical or mental disorder based on current DSM criteria with associated harmful behavior judged likely to recur or lead to other harmful behaviors.
- Applicants with non medical substance use for non specific substance categories (including alcohol and other substances NOT provided in Schedule I-V of Section 202 of the Controlled Substances Act) and diagnosed with substance abuse or dependence based on current DSM criteria with current associated harmful behavior or history of associated harmful behavior judged likely to recur.

Class A Substance Abuse or Dependence for Specific Substances provided in Schedule I-V of Section 202 of the Controlled Substances Act

Applicants with non medical substance use for specific substances provided in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C), and diagnosed with substance abuse or dependence based on current DSM criteria with or without associated harmful behavior.

Class B Current Physical or Mental Disorder with No Associated Harmful Behavior

- Applicants with current diagnosable physical or mental disorder (including alcohol related and other non specific substance categories disorders) based on current DSM criteria with no associated harmful behavior.

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Class B History of Physical or Mental Disorder with Associated Harmful Behavior Unlikely to Recur

- Applicants with history of diagnosable physical or mental disorder (including alcohol related or other non specific substance categories) based on current DSM criteria with associated harmful behavior when the harmful behavior is judged unlikely to recur or lead to other harmful behavior.

Class B Substance Abuse or Dependence in Full Remission

- Applicants diagnosed with full, sustained remission of substance abuse or dependence based on current DSM criteria.

Documentation

The I-693 Medical Examination form must be completed in entirety including diagnosis and classification of mental or physical disorders and substance related disorders.

The original I-693, Report of Medical Examination and Vaccination Record, must be completed in entirety, signed, and placed in a sealed envelope for submission to the Department of Homeland Security (DHS), Citizenship and Immigration Services (CIS) office. This includes assigning a classification on the I-693 if an applicant is Class A or Class B for a physical or mental disorder or substance related disorder.

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For applicants who are referred to a specialist for further evaluation, the civil surgeon is required to retain a copy of the specialist's report along with the I-693 form for their records.

For applicants who are referred for psychological or laboratory testing, the civil surgeon is required to complete Part 3 of the I-693 form. The civil surgeon must also ensure that Part 4 is completed and provides sufficient information to make a diagnosis and classification of a physical or mental disorder, or substance related disorder. The civil surgeon should provide pertinent information regarding referral in the appropriate remarks section in Part 2 or the I-693 form.

A copy of any other documents provided for review regarding the diagnosis or classification of a physical or mental disorder, or substance related disorder for an applicant should be retained by the civil surgeon.

APPENDIX A: GLOSSARY OF ABBREVIATIONS

CDC – Centers for Disease Control and Prevention, United States

DGMQ – Division of Global Migration and Quarantine

DHS - Department of Homeland Security

DOS - Department of State

DSM - Diagnostic and Statistical Manual of Mental Disorders

FDA - Food and Drug Administration

ICD - Manual of the International Classification of Diseases

WHO - World Health Organization

APPENDIX B: USEFUL RESOURCES

American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition.

World Health Organization: *Manual of the International Classification of Diseases*.

APPENDIX C: CONTROLLED SUBSTANCES

Schedules I through V of Section 202 of the Controlled Substances Act are available at the following location: <http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol9/pdf/CFR-2001-title21-vol9-part1308-subjectgroup-id175.pdf> [PDF - 4 pages]  [] .

APPENDIX D: SUMMARY OF MENTAL HEALTH EXAMINATION

Summary

- The purpose of the examination is to identify health-related conditions that render an applicant *inadmissible* and conditions that will need follow-up care.
- Health-related conditions that render an applicant *inadmissible* are -
 - Dependence on (addiction) or abuse of a specific substance provided in Schedule I-V of Section 202 of the Controlled Substances Act.
 - A physical or mental disorder (including alcohol-related disorders) that might cause or has caused harmful behavior.
 - History of physical or mental disorder that has caused harmful behavior and is likely to recur.
- Mental disorders are characterized by alterations in thinking, mood, or behavior.
 - Substance dependence and abuse are determined by DSM criteria.
 - Indicated medical use of a substance is not substance abuse.
 - General mental disorders are determined by DSM criteria.
 - "V" coded conditions are not mental disorder diagnoses.
- Harmful behavior is -

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- Serious psychological or physical injury to others or to the applicant.
- A serious threat to health or safety.
- Major damage to property.
- Harmful behavior alone (without mental or physical disorder) or a mental or physical disorder alone is not a health-related condition that renders an applicant inadmissible.
 - Any antisocial act requires further investigation, but mental disorder diagnoses involve patterns of behavior, not single events.
- The classification (A or B) is used to determine admissibility and the need for follow-up care.
- Remission is determined by DSM criteria.
 - Sustained, full remission for substance-related disorders is at least 12 months.
 - Sustained, full remission is dependent on clinical judgment but requires reliable evidence.
 - A statement signed by the applicant is helpful in documenting –
 - The applicant's understanding of his or her condition, and
 - Requirements to demonstration remission, such clinical reports.
- Harmful behavior unlikely to recur includes the following factors –
 - Remission or control of the mental disorder for at least 12 months.
 - External circumstances influencing that behavior have changed.
- The eligibility to apply for a waiver is determined by law. DHS, USCIS has the final authority to adjudicate the waiver request.

Figures

Figure 1. For Applicant With Medical History of a Physical or Mental Disorder, Next Determine:

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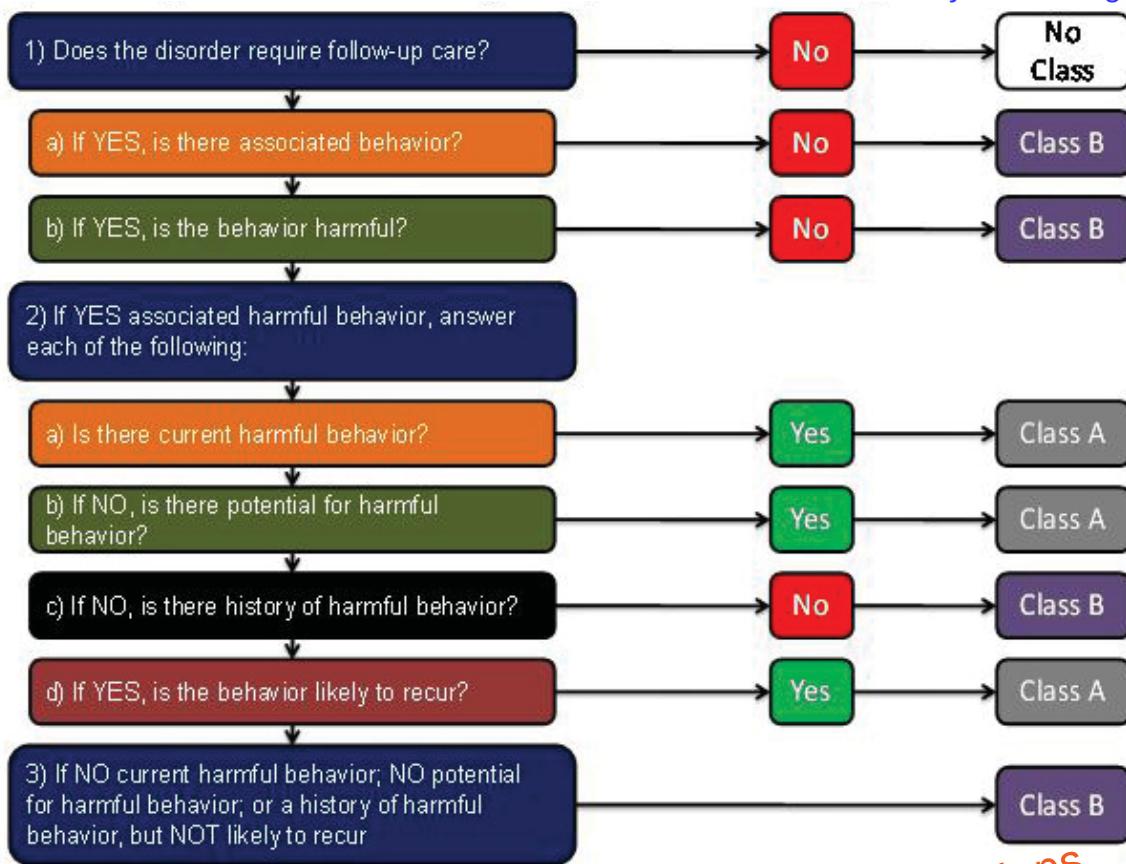
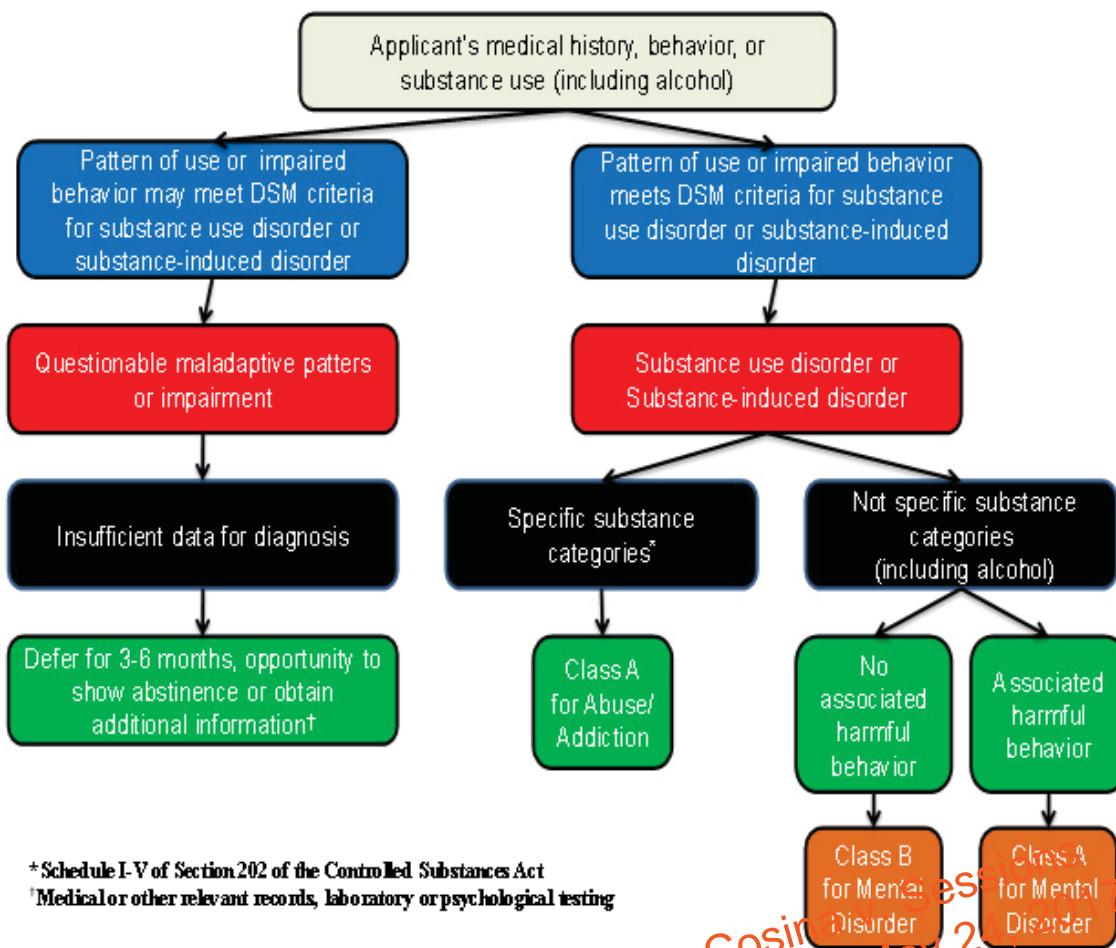


Figure 2. Identifying and Classifying Applicants With Possible Substance Dependence or Abuse

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Tables

Table 1. Indications for Laboratory Drug Screening

Include (but are not limited to) –

- History of any substance abuse or dependence with a specific substance listed in Schedules I through V of Section 202 of the Controlled Substances Act. (See Appendix C)
- Applicant-provided information that appears to contradict information provided by family members or from other records, such as police, military, school, and employment.
- Unexplained gaps of time in the applicant's past schooling or employment.
- Evidence of unreliable or false information given during the interview or examination.
- Any demeanor, presentation, or findings that the examining physician associates with substance abuse or dependence, such as motor ability and interpersonal skills; deepened skin coloring, needle scarring, or skin ulcers along the veins in the arms or legs; or a hard, bumpy, or shrunken liver.
- Evidence or appearance of intoxication with any substance during the examination.
- Disturbed behavior that might be associated with a substance-related disorder.

Table 2. Sustained, Full Remission During the Most Recent 12 Months Before Reexamination

Means that during that interval –

- The civil surgeon has received reliable evidence of the applicant's remission for that time period.
- The applicant did not meet DSM criteria (no behavior) for dependence or abuse.
- The general mental disorder (non-substance related) is under control (by medication or by the natural history of the disorder) and recurrence of specific life events or unusual circumstances that precipitated an episode(s) of illness are judged unlikely to recur.
- The applicant was not in a controlled environment where access to alcohol or drugs was restricted, such as a treatment facility, jail, or halfway house.

Table 3. Factors Affecting the Applicant's Likelihood of Maintaining Remission of a Mental Disorder or Having a Disorder Under Control

- The availability of effective treatments.
- The applicant's faithfulness with previous treatment, willingness to remain on treatment, and his or her insight into disorder. He or she stating in writing a willingness to continue medication or other effective treatment to control the disorder can help demonstrate this.
- The natural history of the disorder (for instance, bipolar mood disorders without ongoing treatment are characterized by multiple episodes of illness and remission).
- The number of and interval between previous episodes of illness (for instance, episodes of schizophrenia with prominent psychotic symptoms were 3 years apart at the beginning of the illness but are now happening every year).
- Any trend towards increasing severity of episodes of illness or emergence of treatment-resistant symptoms.
- The likelihood of recurrence of specific life events that precipitated previous episodes of illness or likelihood of severe life stresses that might precipitate further episodes of illness (for instance, postpartum depression in a young woman).
- Unusual circumstances that precipitated a single episode of illness judged unlikely to recur.

Table 4. Referring Applicant to a Specialist Consultant

The Civil Surgeon may refer the applicant to a specialist consultant if after interview, review of records, and examination, he or she is unable to -

- Arrive at a probable psychiatric diagnosis for purposes of the determination of a mental disorder with associated harmful behavior (past or present)
- Arrive at a probable diagnosis of substance-related disorder according to DSM criteria.
- Arrive at a probable diagnosis for past episodes of mental disorder according to current DSM criteria, or determine that previous difficulties in functioning were the result of a mental disorder.
- Rule out the presence of a mental disorder.
- Determine if harmful behavior has been associated with a physical or mental disorder.
- Determine if any associated harmful behavior is likely to recur.
- Determine if any diagnosed physical or mental disorders that affect behavior are in remission or under control.
- Determine the likelihood of maintaining remission or effective control of diagnosed physical or mental disorders that affect behavior.

Panel Physicians Portal

Related Links

- Immigrant and Refugee Health
- Travelers' Health
- Animal Importation
- Nonpharmaceutical Interventions (NPIs)
- United States–Mexico Public Health
- Quarantine
- Division of Global Migration and Quarantine

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CDC IMMIGRATION REQUIREMENTS:

TECHNICAL INSTRUCTIONS FOR PHYSICAL OR MENTAL DISORDERS WITH ASSOCIATED HARMFUL BEHAVIORS AND SUBSTANCE-RELATED DISORDERS

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases

Division of Global Migration and Quarantine

December 08, 2013

cited in *Ledezma-Cosina v. Sessions*
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CDC IMMIGRATION REQUIREMENTS:

Technical Instructions for Physical or Mental Disorders with Associated Harmful Behaviors and Substance-Related Disorders

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- Table 2. Sustained, Full Remission During the Most Recent 12 Months Before Reexamination
- Table 3. Factors Affecting the Applicant's Likelihood of Maintaining Remission of a Mental Disorder or Having a Disorder Under Control
- Table 4. Referring Applicant to a Specialist Consultant

Preface

Medical screening for physical and mental disorders with associated harmful behaviors and substance-related disorders among persons applying for adjustment of status to permanent resident and other persons required by law to have a medical examination, hereafter referred to as applicants, is an essential component of the immigration-related medical evaluation. Because these conditions are challenging to diagnose and treat, these technical instructions provide a method for recording findings from the medical examination and additional guidance for the civil surgeon in classifying applicants. The new technical instructions use uniform criteria and diagnosis consistent with current medical knowledge and classification connected with legal definitions.

- The required examination includes evaluation of physical and mental disorders with associated harmful behaviors and substance-related disorders. Inadmissibility based on a physical or mental disorder is limited to applicants with associated harmful behavior or potentially harmful behavior.

The Immigration and Nationality Act (INA) provides three grounds of inadmissibility related to substance addiction or abuse, or physical or mental disorders that affect behavior. They are -

- Current physical or mental disorder with associated harmful behavior.
- Past physical or mental disorder with associated harmful behavior if the harmful behavior is likely to recur or to lead to other harmful behavior in the future.
- Drug (substance) abuse or addiction (medically called dependence). Dependence on or abuse of any of the substances listed in Section 202 of the Controlled Substances Act (Appendix C). (The term addiction corresponds with the medical term dependence).

The instructions in this document supersede all previous Technical Instructions, Updates to the Technical Instructions, memoranda and letters to civil surgeons relating to substance abuse or addiction and mental or physical disorders with associated harmful behavior (whether past or present). These new instructions are to be followed when determining whether an applicant is afflicted with physical and mental disorders with associated harmful behaviors and substance-related disorders among all applicants.

For any questions about these Technical Instructions, please contact the Immigrant, Refugee, and Migrant Health Branch of the Division of Global Migration and Quarantine (DGMQ), Centers for Disease Control and Prevention (CDC), at cdcQAP@cdc.gov or 404-498-1600. These Technical Instructions and other information pertinent to them and the medical examination for applicants for U.S. immigration can be found online at <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/civil/technical-instructions-civil-surgeons.html>.

Role of the Civil Surgeon

The purpose of the immigration examination is to identify health-related conditions that render an applicant *inadmissible*, and also to identify and inform the applicant of conditions possibly needing follow-up care.

As part of the medical evaluation and physical examination of the applicant, the civil surgeon will carry out or obtain a mental health evaluation -

- To identify and diagnose any physical or mental disorder (including alcohol-related disorders).
- To identify any harmful behavior associated with a disorder.
- To identify the use of drugs, other than those required for medical reasons, and diagnose any substance-related disorder.
- To determine the remission status of any disorder previously diagnosed.
- To determine the likelihood of recurrence of harmful behaviors associated with a physical or mental disorder.

For most applicants, the civil surgeon's examination will require only one appointment. However, for some applicants multiple appointments or specialist consultations may be required to make an accurate diagnosis of whether the applicant is afflicted with a Class A or Class B condition as it relates to physical or mental disorders with associated harmful behavior or substance abuse and addiction (dependence).

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Key Concepts

A harmful behavior is defined as an action associated with a mental or physical disorder that is or has caused -

- **Serious psychological or physical injury to the applicant or to others (e.g., a suicide attempt or pedophilia)**
- **A serious threat to health or safety (e.g., driving while intoxicated or verbally threatening to kill someone)**
- **Major property damage.**

An applicant who has exhibited harmful behavior not associated with a specific mental or physical disorder is not considered inadmissible under health-related grounds, but may be inadmissible under criminal grounds as determined by DHS/USCIS.

The Diagnostic and Statistical Manual of Mental Disorders' (DSM) diagnosis for substance-related disorders is used in this examination to determine "drug abuse" and "drug addiction" which are listed as a medical ground of inadmissibility in the Immigration and Nationality Act.

Alcohol dependence or abuse alone is not considered a Class A condition. It is considered the same as any other mental disorder, and requires associated harmful behavior to be classified as a medically inadmissible condition.

Physical Disorder

A physical disorder is a clinically diagnosed medical condition where the focus of attention is physical manifestations. Only physical conditions that are included in the current version of the World Health Organization's *Manual of the International Classification of Diseases* (ICD) will be considered for the purpose of this examination.

Mental Disorder

Mental disorders are health conditions that are characterized by alterations in thinking, mood, or behavior (or some combination thereof). The current version of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) is an authoritative source on the classification of mental disorders and should be considered for the purpose of this examination.

“V” Coded Condition

“V” coded conditions listed in the DSM are not diagnoses, but are used in clinical practice settings when the focus of clinical attention is on a behavior that is not due to a mental disorder. Because these “V” conditions are not mental disorders, they cannot be used in determining if a person has an *inadmissible* (Class A) health-related condition, regardless of whether there is an associated harmful behavior. However, behaviors associated with “V” coded conditions might require treatment.

Harmful Behavior

The civil surgeon is to identify any harmful behavior that is associated with an applicant’s physical or mental disorder.

Only harmful behavior that is associated with a physical or mental disorder is relevant for the classification of U.S. medical eligibility; neither harmful behavior by itself nor the physical or mental disorder by itself makes an applicant medically inadmissible. People can have multiple harmful behaviors that are not associated with a physical or mental disorder. Repetitive antisocial activities and harmful acts may warrant evaluation for personality disorders according to DSM criteria, and eventually provide a basis for the conclusion of inadmissibility. Because of the complexity of this issue, the civil surgeon might feel that a more specialized psychiatric examination is indicated. (Table 4)

Substance-Related Disorders

To establish any substance-related disorder diagnosis, the examining physician must document the pattern of use and behavioral, physical, and psychological effects associated with the use or cessation of use of that substance. Diagnoses of substance-related disorders are to be made in accordance with existing medical standards as determined by the current edition of the DSM. In the current DSM, substance-related disorders are divided into the following two groups:

- 1) Substance use disorders
- 2) Substance-induced disorders

For purposes of this evaluation, substances are divided into two groups, controlled substances and non-controlled substances. Controlled substances are any substance listed in Schedules I through V of Section 202 of the Controlled Substances Act. (See Appendix C.) Non-controlled substances include alcohol and all other substances.

Substances used for clinical care in medical practice are not prohibited. Prescription drugs taken in accordance with a prescription do not amount to a substance use disorder. However, abuse of prescription drugs could be a substance-related disorder. This requires a full evaluation by the examining physician to determine whether illicit drugs are being used, because use of illicit drugs is a risk factor for the misuse of prescribed, controlled substances.

Substance Use Disorders

The essential feature of a substance use disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems.

The DSM criteria for substance use disorders fit within overall groupings of *impaired control*, *social impairment*, *risky use*, and *pharmacological criteria*. Pharmacological criteria include tolerance and withdrawal.

Drug (substance) abuse or addiction (medically called dependence) is listed as a medical ground of inadmissibility by the Immigration and Nationality Act (INA). An applicant will be barred from admission if he or she

- Uses a controlled substance
AND
• Meets DSM criteria for a substance use disorder.

The DSM uses the following criteria to determine the severity of a substance use disorder:

- The presence of 2-3 symptoms (this suggests a mild substance use disorder)
- The presence of 4-5 symptoms (this suggests a moderate substance use disorder)
- The presence of 6 or more symptoms (this suggests a severe substance use disorder)

If an applicant's substance use meets criteria for either a mild, moderate, or severe substance use disorder, and involves a controlled substance, the applicant is considered Class A for drug abuse/addiction.

If an applicant's substance use meets the criteria for either a mild, moderate, or severe substance use disorder but involves a non-controlled substance, the civil surgeon should determine whether harmful behavior is present or if there is a history of harmful behavior that is judged likely to recur. If harmful behavior is present or is judged likely to recur, then the applicant is considered Class A for a physical or mental disorder. If the applicant does not currently have harmful behavior or does not have a history of harmful behavior judged likely to recur, the applicant is considered Class B for a physical or mental disorder.

Substance-Induced Disorders

In addition to substance use disorders, the DSM has a separate category called substance-induced disorders. The DSM list of substance-induced disorders includes but is not limited to intoxication, withdrawal, and other substance/medication-induced mental disorders (psychotic disorders, bipolar and related disorders, depressive disorders, anxiety disorders, obsessive-compulsive and related disorders, sleep disorders, sexual dysfunctions, delirium, and neurocognitive disorders/substance-induced psychotic disorder, and substance-induced depressive disorder).

If an applicant's substance use meets the DSM criteria for a substance-induced disorder, and involves the use of a controlled substance, the applicant is considered Class A for drug abuse/addiction.

If an applicant's substance use meets the criteria for a substance-induced disorder but involves a non-controlled substance, the civil surgeon should determine whether harmful behavior is present or if there is a history of harmful behavior that is judged likely to recur. If harmful behavior is present or is judged

likely to recur, then the applicant is considered Class A for a physical or mental disorder. If the applicant does not currently have harmful behavior or a history of harmful behavior judged likely to recur, the applicant is considered Class B for a physical or mental disorder.

Summary of Substance Use Disorders and Substance-Induced Disorders

DSM Diagnosis	Involving Controlled Substance?	Harmful Behavior Associated with Disorder (Current, or History Likely to Recur)?	Classification for Immigration Purposes
Substance use disorder (mild, moderate, or severe)	Yes	N/A- Does not apply	Class A, Drug Abuse/Addiction
Substance use disorder (mild, moderate, or severe)	No	Yes	Class A, Physical/Mental Disorder with Associated Harmful Behavior
Substance use disorder (mild, moderate, or severe)	No	No	Class B, Physical/Mental Disorder without Associated Harmful Behavior
Substance-induced disorder	Yes	N/A-Does not apply	Class A, Drug Abuse/Addiction
Substance-induced disorder	No	Yes	Class A, Physical/Mental Disorder with Associated Harmful Behavior
Substance-induced disorder	No	No	Class B, Physical/Mental Disorder without Associated Harmful Behavior

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Class A and Class B Medical Conditions

Class A medical conditions are *inadmissible* conditions and include an applicant who is determined to have -

- A current physical or mental disorder with associated harmful behavior
- A past physical or mental disorder with associated harmful behavior if the harmful behavior is likely to recur or to lead to other harmful behavior in the future
- Drug (substance) abuse or addiction (dependence)

Class B medical conditions are not inadmissible medical conditions and include any applicant who is determined to have a physical or mental abnormality, disease, or disability serious in degree or nature amounting to a substantial departure from well-being.

Mental Health Examination

Observation alone is not sufficient to assess an applicant.

Random screening for drugs is not part of the routine medical evaluation of applicants for U. S. admission.

If the civil surgeon is unable to determine whether an applicant has a diagnosis of a physical or mental disorder, or substance abuse or dependence for a substance listed in Section 202 of the Controlled Substances Act, diagnosis and classification may be deferred in order to obtain additional medical evidence.

Record DSM diagnoses for mental disorders and substance-related disorders on the I-693 Form under Part 2, in the Remarks for Number 3 and Number 4.

The civil surgeon can recognize that an applicant with a physical or mental disorder might have an associated harmful behavior during any part of the examination.

- While taking the medical history of a mental disorder,
- While taking history of harmful behavior, or
- While observing for current abnormal behavior during the physical examination.

Medical History

The civil surgeon should begin by asking questions about the past medical history of the applicant. To fully investigate the applicant's past medical history, the civil surgeon, when possible, should -

- Obtain other relevant records, such as police, military, school, and employment, that might provide a history of harmful behavior associated with physical or mental disorders.
- Ask about mental disorders in the family and, when appropriate, about signs of mental problems or odd behaviors.
- Ask about any use of drugs and medicines.
- Ask about harmful behaviors.

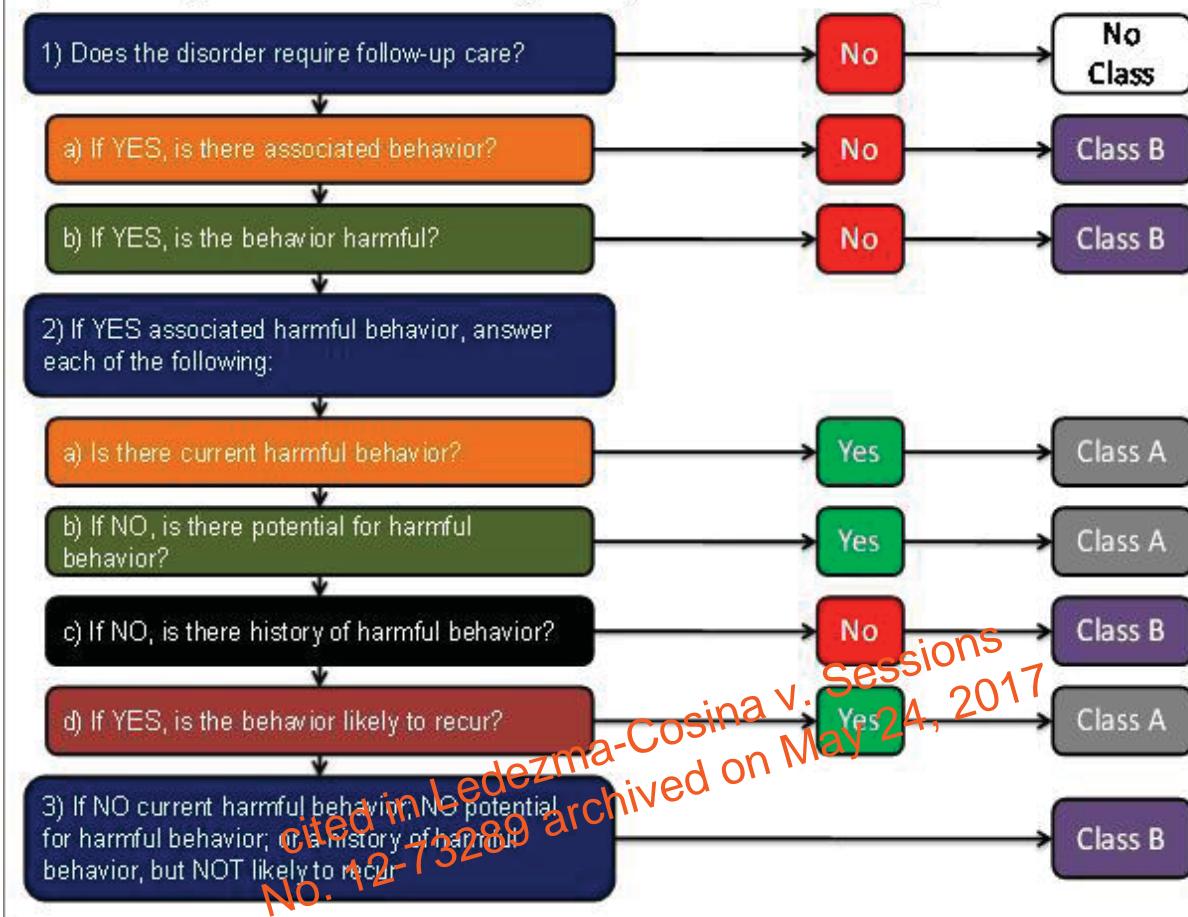
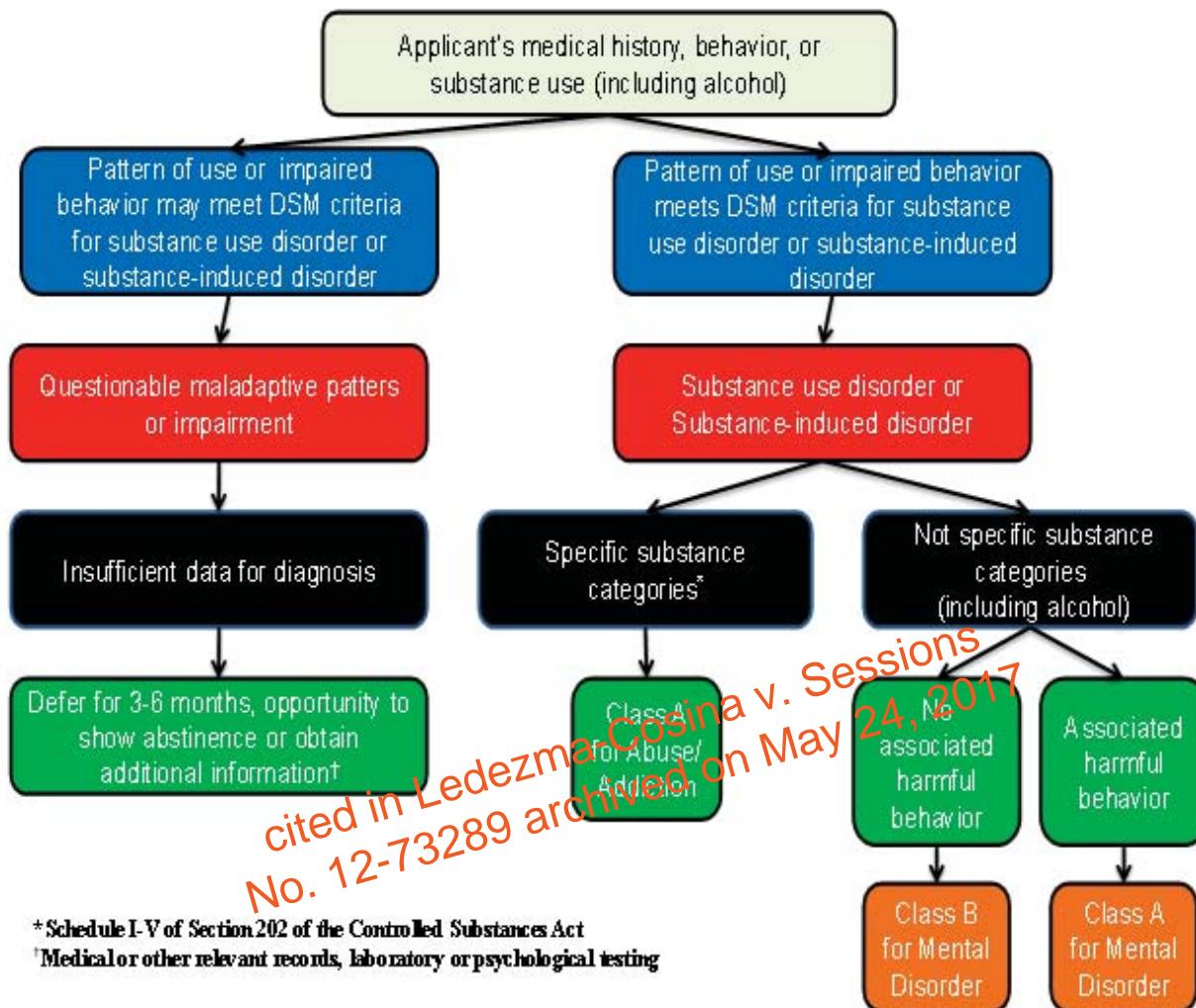
Figure 1. For Applicant With Medical History of a Physical or Mental Disorder, Next Determine:

Figure 2. Identifying and Classifying Applicants With Possible Substance Dependence or Abuse

When a civil surgeon defers diagnosis and classification, the civil surgeon should explain to the applicant what the civil surgeon would like to see during the next 3-6 months (in order to classify the applicant) to show abstinence (see Figure 2). This may include but is not limited to requiring clinical reports from health care professionals for applicants with possible substance-related disorders to demonstrate participation in a drug treatment program. For applicants with deferred diagnosis and classification, the civil surgeon should consider documenting in a statement signed by the applicant the

information he or she is providing to the applicant; the statement should specify what is required during the next 3 to 6 months (see Figure 2) to show abstinence.

Psychiatric Evaluation

The civil surgeon should conduct an activities assessment and mental status examination that assesses, at a minimum -

- orientation,
- mood and affect,
- speech and language,
- anxiety,
- thought processes and content, and
- behavior.

The civil surgeon may estimate the degree of cognitive impairment in dementia or mental retardation by assessing the applicant's (1) level of knowledge, and (2) ability to carry out functions of daily living (e.g., learning, communication, and routine activities).

Any available reports of cognitive, development, or intelligence testing, or neuropsychological testing in the medical record are welcome and may be included with the civil surgeon's report. However, the civil surgeon is not asked to routinely send applicants for additional psychological tests.

Under most circumstances, the civil surgeon or consultant will not need to provide additional psychological or neuropsychological testing. Use of projective instruments, such as Rorschach test, may not be useful given the added administrative burden involved. No psychological or neuropsychological testing is a substitute for the civil surgeon's or consultant's history and examination of the applicant. However, for certain cases, these tests may aid in making a diagnosis.

Laboratory Testing

Random screening for drugs is not part of the routine medical examination for applicants for U.S. admission. The civil surgeon needs to evaluate the applicant's history, behavior and physical appearance when determining if drug screening should be performed.

Whole populations of applicants should not routinely be subject to random laboratory screening. The civil surgeon should make an individual decision based on the indications for drug screening (see Table 1).

Laboratory testing to identify underlining medical conditions that might be causing psychiatric manifestations may be necessary before making any mental disorder diagnoses. However, specialized laboratory testing, such as dexamethasone suppression tests or challenge administration of various pharmaceuticals, is usually not indicated in the diagnosis of applicants.

Other possible uses of laboratory support depend on the availability of such laboratory services and the clinical judgment of the civil surgeon as to their usefulness in classification of the individual applicant.

For example, therapeutic levels of prescribed anticonvulsant medications, antipsychotic medications, or other medicines used in psychiatry (such as lithium levels) might be of value to the civil surgeon in -

- Determining the applicant's adherence to a prescribed course of treatment.
- Possibly changing or adjusting the applicant's medications, and therefore contributing to remission of illness and reduction of associated harmful behavior.

Random screening for drugs on short notice to the applicant can provide additional evidence to aid in diagnosis and classification. For example, the civil surgeon might request that three random screenings for drugs within a 3- to 6-month period be done with only 24- to 48-hour notification to the applicant. The period of advance notification should be the minimum practical time for the applicant to arrive at the screening facility, preferably 24 or 48 hours after notification.

Table 1. Indications for Laboratory Drug Screening

Include (but are not limited to) -

- History of any substance abuse or dependence with a specific substance listed in Schedules I through V of Section 202 of the Controlled Substances Act. (See Appendix C)
- Applicant-provided information that appears to contradict information provided by family members or from other records, such as police, military, school, and employment.
- Unexplained gaps of time in the applicant's past schooling or employment.
- Evidence of unreliable or false information given during the interview or examination.
- Any demeanor, presentation, or findings that the examining physician associates with substance abuse or dependence, such as motor ability and interpersonal skills; deepened skin coloring, needle scarring, or skin ulceration along the veins in the arms or legs; or a hard, bumpy, or shrunken liver.
- Evidence or appearance of intoxication with any substance during the examination.
- Disturbed behavior that might be associated with a substance-related disorder.
- Follow-up of an initial positive drug screen or a history of a positive drug-screening test.

It is the civil surgeon's responsibility to know the reliability and validity of the laboratory tests and laboratory methods used during the medical evaluation. All drug testing is to be done by using materials licensed by the U.S. Food and Drug Administration or by the equivalent licensing office in other countries. Rapid testing or semi-quantitative testing may be used for the screening test; however, gas chromatography/mass spectrometry (GC/MS), performed at a reference laboratory, needs to be used as the confirmatory test. Positive and negative controls must be used with any testing and only test kits that are for medical diagnosis and treatment must be used. Forensic testing is minimally regulated and will be labeled "not for medical diagnosis and treatment" and, therefore, should not be used because it is not sensitive enough for medical purposes.

Mental or Physical Disorders With Associated Harmful Behavior

Only mental or physical disorders during which the applicant engages in or has engaged in harmful behavior that is associated with (due to) the mental or physical disorder will make an applicant inadmissible. As previously stated, no diagnosis of a mental or physical disorder by itself provides a basis for inadmissibility. There must also be a determination made regarding current harmful behavior or a history of harmful behavior, associated with or caused by the disorder, and the likelihood of associated harmful behavior to recur, in order to provide basis for inadmissibility.

Thus, when evaluating an applicant for possible mental disorders, it is vital to assess for the likelihood of harmful behavior. Because there are mental disorders that are commonly associated with harmful behavior, it may be helpful to first look for the harmful behavior when assessing an applicant for a possible mental disorder. (See Figure 1)

Mental disorders most frequently associated with harmful behavior include -

- major depression,
- bipolar disorder,
- schizophrenia, and
- mental retardation.

These disorders occur within broader categories of disorders that can be grouped as -

- Mood disorders that include major depression and bipolar disorders and can be associated with high rates of suicide and aggression.
- Anxiety disorders that include post-traumatic stress disorder, panic disorders, phobias, and anxiety disorders and can be associated with harmful behavior.
- Personality disorders that include antisocial, paranoid, and borderline personality disorders and can be associated with impulsive acts of violence.
- Sexual disorders that include paraphilic acts.
- Schizophrenia and other psychotic disorders that can be associated with delusions, paranoia, suicide, and aggressive acts.
- Disorders usually first diagnosed in childhood that include mental retardation and conduct disorder and are often associated with harmful behaviors. In addition, other cognitive disorders, such as dementia, can be associated with harmful behaviors.
- Substance-related disorders that include substance dependence or abuse. For specific substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C), no associated harmful behavior is required for the applicant to have a medically inadmissible condition based on substance abuse/dependence (please see above for the determination of substance abuse/dependence). The civil surgeon is reminded that for substances not listed in Schedule I-V (such as alcohol), that abuse or dependence is evaluated as a mental disorder and determination of associated harmful behavior is required for applicant to have a medically inadmissible condition. With alcohol dependence or abuse there is often associated harmful behavior during periods of intoxication and withdrawal.

Physical Disorder

Physical disorders are rarely associated with harmful behavior. It may happen in delirious or confused states due to metabolic disturbances, hypoglycemia; and some psychomotor epilepsies and in the

aftermath of generalized seizure disorders and various forms of seizure disorders. When evaluating an applicant for a physical disorder with associated harmful behavior, the civil surgeon should diagnosis physical disorders according to the conventions used in the current edition of the ICD published by the World Health Organization.

Current Harmful Behavior

If the applicant is currently engaging in harmful behavior, that is, harmful behavior (see definition above) that has continuously occurred and seems ongoing, the civil surgeon must evaluate whether the actions may be indicative of a mental disorder.

Future Harmful Behavior

If the applicant presently is or in the past has engaged in harmful behavior associated with a physical or mental disorder, the civil surgeon must evaluate whether the harmful behavior is likely to recur. Many factors enter into this determination of classification, and the decision requires clinical judgment. At a minimum, the underlying physical or mental disorder must be either in remission or reliably controlled by medication or other effective treatment.

As a general guideline, when a mental or physical disorder has a favorable prognosis and is in remission or under control but there was associated harmful behavior, if it has been 12 months since the harmful behavior occurred, the harmful behavior is less likely to recur (see Table 3).

Remission

The current version of the DSM defines sustained, full remission as a period of at least 12 months during which no substance use or mental disorder-associated behaviors have occurred. These new technical instructions reflect the current medical knowledge and standards of the DSM. The panel physician and his or her consultant must use their clinical judgment in determining if 12 months is an acceptable period of time for the individual applicant to demonstrate sustained, full remission. This time period must be based on the reliability of the evidence provided, such as clinical reports of participation in a program, such as a drug treatment program.

Remission must also be considered in two contexts: (1) general mental disorders and (2) substance-related disorders.

For general mental disorders, the determination of remission must be made based on the assessment of associated harmful behavior, either current or history of judged likely to recur and DSM criteria. This includes substance-related disorders for those substances, including alcohol, not listed in Schedules I through V of Section 202 of the Controlled Substances Act.

For substance-related disorders for those substances listed in Schedule I through V of Section 202 of the Controlled Substances Act, the determination of remission must be made based on applicant's substance use and DSM criteria.

The practical significance for diagnosis of remission is that applicants who are or have been determined to be Class A for abuse or addiction for those substances listed in Schedule I through V of Section 202 of the Controlled Substance Act are not eligible for a waiver and must complete the time period for sustained, full remission before reapplying for admission.

The civil surgeon must exercise judgment in reevaluating applicants with a previous Class A determination who are reapplying for admission. If the disorder is in the past, the decision is whether to classify the applicant as Class A or B. If the disorder is current, the decision becomes whether the applicant is still Class A or is in a period of remission sufficient to lend confidence that remission is sustained and full. In other words, if the applicant is currently in remission, what is the likelihood that the remission will be sustained? (See Table 2)

Table 2. Sustained, Full Remission During the Most Recent 12 Months Before Reexamination

Means that during that interval -

- The civil surgeon has received reliable evidence of the applicant's remission for that time period.
- The applicant did not meet DSM criteria (no behavior) for dependence or abuse.
- The general mental disorder (non-substance related) is under control (by medication or by the natural history of the disorder) and recurrence of specific life events or unusual circumstances that precipitated an episode(s) of illness are judged unlikely to recur.
- The applicant was not in a controlled environment where access to alcohol or drugs was restricted, such as a treatment facility, jail, or halfway house.
- No use other than indicated medical treatment of any of the substances listed in Schedules I-V of Section 202 of the Controlled Substances Act.

Sexually Dangerous People

Not all sexually dangerous people have behaviors attributable to a psychiatric or general medical disorder. For instance, rapist is not a psychiatric diagnosis. However, people diagnosed with paraphilic disorders might commit rape when their intense sexual fantasy, urge, or fetish is enacted with a child or other non-consenting person. People who have harmful behaviors associated with sexual acts, whether reported as a criminal act or psychiatric disorder, have been shown not to benefit reliably from treatment programs. Documented or acknowledged episodes of paraphilia might represent only a fraction of the sexually dangerous person's history of related harmful behaviors. Given the pattern of recurring harmful behaviors in paraphilia and the high relapse rate of sexual offenders, applicants with a history of harmful behavior associated with sexual acts are almost always likely to have a recurrence of harmful behavior and therefore remain medically classifiable as a Class A mental disorder with associated harmful behavior.

Table 3. Factors Affecting the Applicant's Likelihood of Maintaining Remission of a Mental Disorder or Having a Disorder Under Control -

- The availability of effective treatments.
- The applicant's faithfulness with previous treatment, willingness to remain on treatment, and his or her insight into disorder. He or she stating in writing a willingness to continue medication or other effective treatment to control the disorder can help demonstrate this.
- The natural history of the disorder (for instance, bipolar mood disorders without ongoing treatment are characterized by multiple episodes of illness and remission).
- The number of and interval between previous episodes of illness (for instance, episodes of schizophrenia with prominent psychotic symptoms were 3 years apart at the beginning of the illness but are now happening every year).
- Any trend towards increasing severity of episodes of illness or emergence of treatment-resistant symptoms.
- The likelihood of recurrence of specific life events that precipitated previous episodes of illness or likelihood of severe life stresses that might precipitate further episodes of illness (for instance, postpartum depression in a young woman).
- Unusual circumstances that precipitated a single episode of illness judged unlikely to recur.

Referring the Applicant to a Specialist for Psychiatric Examination

After reviewing the applicant's available records (such as medical, psychiatric, police, military, school, and employment) and performing mental status and physical examinations (including an Activities Assessment and Mental Status Assessment), the civil surgeon may feel that a more specialized psychiatric examination is indicated. (See Table 4)

If an applicant has been referred to a specialist for psychiatric evaluation and the civil surgeon still needs guidance and assistance in determining the diagnosis and classification of a Class A or Class B or No Class A or Class B condition, DGMQ may be consulted to provide additional assistance.

A copy of all the pertinent medical information may be faxed to 404-639-4441, sent via secure files to cdcQAP@cdc.gov, or mailed to the following address:

Quality Assessment Program
 Division of Global Migration and Quarantine
 Centers for Disease Control and Prevention, Mailstop E-03
 1600 Clifton Road, Atlanta, Georgia 30333, USA

Table 4. Referring Applicant to a Specialist Consultant

The Civil Surgeon may refer the applicant to a specialist consultant if after interview, review of records, and examination, he or she is unable to -

- Arrive at a probable psychiatric diagnosis for purposes of the determination of a mental disorder with associated harmful behavior (past or present)
- Arrive at a probable diagnosis of substance-related disorder according to DSM criteria.
- Arrive at a probable diagnosis for past episodes of mental disorder according to current DSM criteria, or determine that previous difficulties in functioning were the result of a mental disorder.
- Rule out the presence of a mental disorder.
- Determine if harmful behavior has been associated with a physical or mental disorder.
- Determine if any associated harmful behavior is likely to recur.
- Determine if any diagnosed physical or mental disorders that affect behavior are in remission or under control.
- Determine the likelihood of maintaining remission or effective control of diagnosed physical or mental disorders that affect behavior.

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Mental Health Screening Results

The mental health screening is complete when all required aspects of the medical examination have been finalized, including if indicated, the report of the specialist and laboratory test results. At this time, the civil surgeon should be able to assign to the applicant a classification regarding a physical or mental disorder or substance-related disorder.

For physical or mental disorders with associated harmful behavior (past and present), or substance-related disorders, the civil surgeon should use the below outlined screening results to classify applicants as Class A or Class B.

Pertinent information relating to physical or mental disorders, and substance related disorders should be indicated on the I-693.

Screening Results

- Applicants without findings suggestive of mental or physical disorders, or substance abuse or addiction. (No Class A or B Physical or Mental Disorder, No Class A or B Drug Abuse/Addiction).
- Applicants with physical and mental disorders that affect behavior but no associated harmful behavior, and who do not have substance abuse or addiction. (No Class A or B Physical or Mental Disorder, No Class A or B Drug Abuse/Addiction).
- Applicants with “addiction” (dependence) or abuse of any of the substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C) with or without associated harmful behavior. (Class A Substance (Drug) Use, Listed in Section 202 of the Controlled Substance Act.). Applicants may not apply for a waiver of eligibility.
- Applicants with a diagnosis of a current physical or mental disorder (including other substance-related disorders such as alcohol-related disorders) with associated harmful behavior. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with a history of a physical or mental disorder (including other substance-related disorders, such as alcohol-related disorders) with associated harmful behavior and whose harmful behavior is likely to recur or lead to other harmful behavior. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with a history of alcohol-related arrests or convictions (e.g., driving under the influence [DUI]) who currently continues to drink alcohol and who meets DSM criteria for alcohol abuse. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with single alcohol related arrest or conviction within the last five years, or two or more arrests or convictions within the last ten years should be evaluated for alcohol abuse (mental health classification pending).
- Applicants who meet DSM criteria for mood disorders or schizophrenic disorders with associated harmful behavior, either current or judged likely to recur. (Class A, Physical/Mental Disorder with Associated Harmful Behavior).
- Applicants with sustained, full remission of “addiction” (dependence) or abuse of any of the specific substances listed in Schedule I-V of Section 202 of the Controlled Substances Act (see

Appendix C) may be assigned a Class B, Prior Substance (Drug) Use in Remission.

- Applicants with a history of a diagnosable physical or mental disorder (including other substance-related disorders, such as alcohol-related disorders) with associated harmful behavior when the harmful behavior is judged unlikely to recur or lead to other harmful behavior may be assigned a Class B, Physical/Mental Disorder without Associated Harmful Behavior.
- Applicants who are diagnosed with a physical disorder that affects behavior or a mental disorder (including substance-related disorders) that is significant enough to require clinical attention but who have had no associated harmful behavior (such as those with seizure disorders, mental retardation, or schizophrenia without associated harmful behavior) may be assigned a Class B, Physical/Mental Disorder without Associated Harmful Behavior.
- Applicants with history of alcohol related arrests or convictions that currently meets DSM criteria for full, sustained remission, may be assigned a Class B Physical/Mental Disorder Without Associated Harmful Behavior.
- Applicant with a current or past history of mood disorders or schizophrenic disorders without associated harmful behavior may be assigned a Class B Physical/Mental Disorder Without Associated Harmful Behavior.
- Applicants with history of non-medical use of specific categories of substances that currently meets DSM criteria for full, sustained remission may be assigned a Class B, Prior Substance (Drug) Use in Remission.

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Waivers

A provision allows applicants diagnosed with a mental or physical disorder with associated harmful behavior to apply for a Class A waiver.

Most applicants diagnosed with substance abuse or addiction are not eligible to apply for a Class A waiver.

Applicants diagnosed with substance abuse or addiction who are subsequently found to be in remission and reclassified as Class B do not need to apply for a waiver.

A provision allows applicants with a Class A physical disorder or mental disorder with associated harmful behavior to petition for a Class A waiver. Form I-601 or I-602 (for immigrants or refugees, respectively) must be completed. These waivers are submitted to the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) on an individual basis. DGMO also reviews the waivers and supporting medical examination to provide an opinion regarding the case to the requesting entity (DOS or DHS, USCIS). DGMO's review of the waiver and supporting medical examination documentation is to ensure that the applicant has been classified properly and that an appropriate U.S. health care provider is identified for the applicant. DHS, USCIS has the final authority to adjudicate the waiver request.

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Most applicants diagnosed with substance abuse or addiction (dependence) for specific substance categories based on current DSM criteria and classified as Class A are not eligible for a waiver.

Applicants who were previously diagnosed as Class A for substance abuse or addiction and subsequently found to be in remission and reclassified as Class B do not require a waiver.

Mental Health and Substance Abuse/Addiction Classifications and Descriptions

Applicants may be assigned one or more mental or physical disorders with associated harmful behavior and substance-related disorders classification on the I-693 Form.

The physical and mental disorders with associated harmful behaviors and substance related disorders are listed below. Applicants may have more than one classification. However, applicants cannot be classified as both Class A and Class B for the same physical or mental disorder, or substance related disorder.

No Class A or Class B Classification

- Applicants with no diagnosis of physical or mental disorder or substance related disorder.
- Applicants diagnosed with physical and mental disorders based on current DSM criteria that affect behavior but do not meet criteria for Class A or Class B.

Class A Physical or Mental Disorder with Associated Harmful Behavior

- Applicants diagnosed with current physical or mental disorder based on current DSM criteria with associated harmful behavior.
- Applicants diagnosed with history of physical or mental disorder based on current DSM criteria with associated harmful behavior judged likely to recur or lead to other harmful behaviors.
- Applicants with non medical substance use for non specific substance categories (including alcohol and other substances NOT provided in Schedule I-V of Section 202 of the Controlled Substances Act) and diagnosed with substance abuse or dependence based on current DSM criteria with current associated harmful behavior or history of associated harmful behavior judged likely to recur.

Class A Substance Abuse or Dependence for Specific Substances provided in Schedule I-V of Section 202 of the Controlled Substances Act

Applicants with non medical substance use for specific substances provided in Schedule I-V of Section 202 of the Controlled Substances Act (see Appendix C), and diagnosed with substance abuse or dependence based on current DSM criteria with or without associated harmful behavior.

Class B Current Physical or Mental Disorder with No Associated Harmful Behavior

- Applicants with current diagnosable physical or mental disorder (including alcohol related and other non specific substance categories disorders) based on current DSM criteria with no associated harmful behavior.

Class B History of Physical or Mental Disorder with Associated Harmful Behavior Unlikely to Recur

- Applicants with history of diagnosable physical or mental disorder (including alcohol related or other non specific substance categories) based on current DSM criteria with associated harmful behavior when the harmful behavior is judged unlikely to recur or lead to other harmful behavior.

Class B Substance Abuse or Dependence in Full Remission

- Applicants diagnosed with full, sustained remission of substance abuse or dependence based on current DSM criteria.

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Documentation

The I-693 Medical Examination form must be completed in entirety including diagnosis and classification of mental or physical disorders and substance related disorders.

The original I-693, Report of Medical Examination and Vaccination Record, must be completed in entirety, signed, and placed in a sealed envelope for submission to the Department of Homeland Security (DHS), Citizenship and Immigration Services (CIS) office. This includes assigning a classification on the I-693 if an applicant is Class A or Class B for a physical or mental disorder or substance related disorder.

For applicants who are referred to a specialist for further evaluation, the civil surgeon is required to retain a copy of the specialist's report along with the I-693 form for their records.

For applicants who are referred for psychological or laboratory testing, the civil surgeon is required to complete Part 3 of the I-693 form. The civil surgeon must also ensure that Part 4 is completed and provides sufficient information to make a diagnosis and classification of a physical or mental disorder, or substance related disorder. The civil surgeon should provide pertinent information regarding referral in the appropriate remarks section in Part 2 on the I-693 form.

A copy of any other documents provided for review regarding the diagnosis or classification of a physical or mental disorder, or substance related disorder for an applicant should be retained by the civil surgeon.

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APPENDIX A: GLOSSARY OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention, United States
DGMQ	Division of Global Migration and Quarantine
DHS	Department of Homeland Security
DOS	Department of State
DSM	Diagnostic and Statistical Manual of Mental Disorders
FDA	Food and Drug Administration
ICD	Manual of the International Classification of Diseases
WHO	World Health Organization

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APPENDIX B: USEFUL RESOURCES

American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition.

World Health Organization: *Manual of the International Classification of Diseases*.

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APPENDIX C: CONTROLLED SUBSTANCES

Schedules I through V of Section 202 of the Controlled Substances Act are provided below and also available at the following location: <http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol9/pdf/CFR-2001-title21-vol9-part1308-subjectgroup-id175.pdf>

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and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 51 FR 15318, Apr. 23, 1986; 62 FR 13968, Mar. 24, 1997.]

SCHEDULES
§ 1308.11 Schedule I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of paragraph (b)(34) only, the term isomer includes the optical and geometric isomers):

- (1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide) 9815
- (2) Acetylmethadol 9801
- (3) Allyprodine 9802

(4) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadol acetate, or LAAM)	9803
(5) Alphamprodine	9804
(6) Alphamethadol	9805
(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]-propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine)	9814
(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)	9832
(9) Benzethidine	9806
(10) Betacetylmethadol	9807
(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide)	9830
(12) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide)	9831
(13) Betamprodine	9808
(14) Betamethadol	9809
(15) Betaprodine	9811
(16) Clonitazene	9812
(17) Dextromoramide	9813
(18) Diamprodine	9815
(19) Diethylthiambutene	9816
(20) Difenoxin	9188
(21) Dimenoxadol	9817
(22) Dimepheptanol	9818
(23) Dimethylthiambutene	9819
(24) Dioxaphetyl butyrate	9821
(25) Dipipanone	9822
(26) Ethylmethylthiambutene	9823
(27) Etonitazene	9824
(28) Etoxeridine	9825
(29) Furethidine	9826
(30) Hydroxypethidine	9827
(31) Ketobemidone	9828
(32) Levomoramide	9829
(33) Levophenacylmorphan	9831
(34) 3-Methylfentanyl (N-[2-methyl-1-(2-phenylethyl)-4-piperidinyl]-N-phenylpropanamide)	9813
(35) 3-methoxyfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidinyl]-N-phenylpropanamide)	9833
(36) Morperidine	9832
(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9861
(38) Noracymethadol	9833
(39) Norlevorphanol	9834
(40) Normethadone	9835
(41) Norpinapone	9836
(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide	9812
(43) PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine	9863
(44) Phenadoxone	9837
(45) Phenamprodine	9838
(46) Phenomorphan	9847
(47) Phenoperidine	9841
(48) Pirtramide	9842
(49) Proheptazine	9843
(50) Properidine	9844
(51) Propiram	9849
(52) Racemoramide	9845
(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide	9835
(54) Tildine	9750
(55) Trimeperidine	9846

(c) *Opium derivatives.* Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Drug Enforcement Administration, Justice

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(1) Acetorphine	9319	(12) N-hydroxy-3,4-methylenedioxymphetamine (also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA)	7402
(2) Acetylhydrocodeine	9051	(13) 3,4,5-trimethoxy amphetamine	7390
(3) Benzylmorphine	9052	(14) Bufotenine	7433
(4) Codeine methylbromide	9070	Some trade and other names: 3-(β -dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indol; N,N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine	7434
(5) Codeine-N-Oxide	9053	(15) Diethyltryptamine	7435
(6) Cyrenorphine	9054	Some trade and other names: N,N-Diethyltryptamine; DET	7260
(7) Desomorphine	9055	(16) Dimethyltryptamine	7315
(8) Dihydromorphine	9145	Some trade or other names: DMT	7360
(9) Drotebanol	9335	(17) Ibogaine	7381
(10) Etorphine (except hydrochloride salt)	9056	Some trade and other names: 7-Ethyl-6,8,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga	7415
(11) Heroin	9200	(18) Lysergic acid diethylamide	7482
(12) Hydromorphone	9301	(19) Marijuana	7484
(13) Methyldesorphine	9302	(20) Mescaline	7437
(14) Methyldihydromorphine	9304	(21) Parahexyl—7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl	7438
(15) Morphine methylbromide	9305	(22) Peyote	7370
(16) Morphine methylsulfonate	9306	Meaning all parts of the plant presently classified botanically as <i>Lophophora williamsii</i> Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or extracts (Interprets 21 USC 812(c), Schedule I, (2))	7417
(17) Morphine-N-Oxide	9307	(23) N-(3-piperidyl)benzilate	7484
(18) Myrophine	9308	(25) Psilocybin	7437
(19) Nicocodeine	9309	(26) Psilocymin	7438
(20) Nicomorphine	9312	(27) Tetrahydrocannabinols	7455
(21) Normorphine	9313	Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of <i>Cannabis</i> , sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:	7456
(22) Pholcodine	9314	Δ1 cis or trans tetrahydrocannabinol, and their optical isomers	7457
(23) Thebacon	9315	Δ6 cis or trans tetrahydrocannabinol, and their optical isomers	7458
(d) <i>Hallucinogenic substances.</i> Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):		Δ3,4 cis or trans tetrahydrocannabinol, and its optical isomers	7459
(1) Alpha-ethyltryptamine	7249	(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)	7460
Some trade or other names: tryptamine; Monase; α -ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl)indole; α -ET; and AET.		(28) Ethylamine analog of phencyclidine	7455
(2) 4-bromo-2,5-dimethoxy-amphetamine	7391	Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE	7456
Some trade or other names: 4-bromo-2,5-dimethoxy- α -methylphenethylamine; 4-bromo-2,5-DMA		(29) Pyrrolidine analog of phencyclidine	7458
(3) 4-Bromo-2,5-dimethoxyphenethylamine	7392	Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCP, PHP	7459
Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus.		(30) Thiophene analog of phencyclidine	7470
(4) 2,5-dimethoxyamphetamine	7396	Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TCP, TCP	7471
Some trade or other names: 2,5-dimethoxy- α -methylphenethylamine; 2,5-DMA		(31) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine	7473
(5) 2,5-dimethoxy-4-ethylamphetamine	7399	Some other names: TCP	7474
Some trade or other names: DOET			
(6) 4-methoxyamphetamine	7411		
Some trade or other names: 4-methoxy- α -methylphenethylamine; paramethoxyamphetamine, PMA			
(7) 5-methoxy-3,4-methylenedioxy-amphetamine	7401		
(8) 4-methyl-2,5-dimethoxy-amphetamine	7395		
Some trade and other names: 4-methyl-2,5-dimethoxy- α -methylphenethylamine; "DOM"; and "STP"			
(9) 3,4-methylenedioxy amphetamine	7400		
(10) 3,4-methylenedioxymethamphetamine (MDMA)	7405		
(11) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA)	7404		

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(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains

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any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate)	2010
(2) Mecloqualone	2572
(3) Methaqualone	2565

(f) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex (Some other names: aminoaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine)	1585
(2) Cathinone	1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone	
(3) Fenethylline	1503
(4) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-methylaminopropiophenone; monoacetyl-cathinone; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-483 and UR1432), its salts, optical isomers and salts of optical isomers	1237
(5) (±)cis-4-methylaminorex ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine)	1590
(6) N-ethylamphetamine	1475
(7) N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine)	1480

(g) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers	9818
(2) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thienylfentanyl), its optical isomers, salts and salts of isomers	9834

[39 FR 22141, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

21 CFR Ch. II (4-1-01 Edition)**§ 1308.12 Schedule II.**

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

(1) Raw opium	9600
(2) Opium extract	9610
(3) Opium Acid	9620
(4) powdered opium	9639
(5) Granulated opium	9640
(6) Tincture of opium	9630
(7) Codeine	9050
(8) Dihydroetorphine	9334
(9) Ethylmorphine	9190
(10) Etorphine hydrochloride	9059
(11) Hydrocodone	9193
(12) Hydromorphone	9150
(13) Metopon	9260
(14) Morphine	9300
(15) Oxycodone	9143
(16) Oxymorphone	9652
(17) Thebaine	9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances

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shall not include decocainized coca leaves or extraction of coca leaves, whhch extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) *Opiates*. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

(1) Alfentanil	9737
(2) Alphaprodine	9010
(3) Anileridine	9020
(4) Bezitramide	9800
(5) Bulk dextropropoxyphene (non-dosage forms)	9273
(6) Carfentanil	9743
(7) Dihydrocodeine	9120
(8) Diphenoxylate	9170
(9) Fentanyl	9801
(10) Isomethadone	9226
(11) Levo-alpha-acetylmethadol	9648
[Some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM]	
(12) Levomethorphan	9210
(13) Levorphanol	9201
(14) Metazocine	9240
(15) Methadone	9250
(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4-phenyl butane	9254
(17) Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid	9802
(18) Pethidine (meperidine)	9230
(19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
(20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
(21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
(22) Phenazocine	9715
(23) Piminodine	9730
(24) Racemethorphan	9732
(25) Racemorphan	9733
(26) Remifentanil	9739
(27) Sufentanil	9740

(d) *Stimulants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers	1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers	1105
(3) Phenmetrazine and its salts	1631
(4) Methylphenidate	1724

(e) *Depressants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital	2125
(2) Glutethimide	2550
(3) Pentobarbital	2270
(4) Phencyclidine	7471
(5) Secobarbital	2315

(f) Hallucinogenic substances.

(1) Nabilone	7379
[Another name for nabilone: (±)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one]	

(g) *Immediate precursors*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

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(1) Immediate precursor to amphetamine and methamphetamine:

(i) Phenylketone	8501
[Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;]	

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine	7480
(ii) 1-piperidinocyclohexanecarbonitrile (PCC)	8603

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Stimulants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on

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the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
 (2) Benzphetamine 1228
 (3) Chlorphentermine 1645
 (4) Clortermine 1647
 (5) Phendimetrazine 1615

(c) *Depressants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:
 (i) Amobarbital 2126
 (ii) Secobarbital 2316
 (iii) Pentobarbital 2271
 or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
 (2) Any suppository dosage form containing:
 (i) Amobarbital 2126
 (ii) Secobarbital 2316
 (iii) Pentobarbital 2271
 or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
 (3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof 2100
 (4) Chlorhexadol 2510
 (5) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act 2012
 (6) Ketamine, its salts, isomers, and salts of isomers 7285
 [Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone]
 (7) Lysergic acid 7300
 (8) Lysergic acid amide 7310
 (9) Methyprylon 2575
 (10) Sulfondiethylmethane 2600
 (11) Sulfonethylmethane 2605
 (12) Sulfonmethane 2610
 (13) Tiletamine and zolazepam or any salt thereof 7295
 Some trade or other names for a tiletamine-zolazepam combination product:
 Telazol.
 Some trade or other names for tiletamine:
 2-(ethylamino)-2-(2-thienyl)-cyclohexanone.
 Some trade or other names for zolazepam:
 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, fluprazapon.

(d) Nalorphine 9400.

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(e) *Narcotic Drugs*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803
 (2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804
 (3) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805
 (4) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts 9806
 (5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts 9807
 (6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts 9808
 (7) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9809
 (8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

(f) *Anabolic steroids*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids 4000

(g) *Hallucinogenic substances*.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.

[Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran-1-ol] or (-)-delta-9-(trans)-tetrahydrocannabinol]

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(2) [Reserved]

[39 FR 22142, June 20, 1974, as amended at 41 FR 43401, Oct. 1, 1976; 43 FR 3359, Jan. 25, 1978; 44 FR 40888, July 13, 1979; 46 FR 52334, Oct. 27, 1981; 51 FR 5320, Feb. 13, 1986; 52 FR 2222, Jan. 21, 1987; 52 FR 5952, Feb. 27, 1987; 56 FR 5754, Feb. 13, 1991; 56 FR 11932, Mar. 21, 1991; 62 FR 13968, Mar. 24, 1997; 64 FR 35930, July 2, 1999; 64 FR 37675, July 13, 1999; 65 FR 13238, Mar. 13, 2000; 65 FR 17440, Apr. 3, 2000]

§ 1308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit 9167
 (2) Dextropropoxyphene (alpha-(+)-4-(dimethylamino)-1,2-diphenyl-3-methyl-2-propoxybutane) 9278

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam 2882
 (2) Barbital 2145
 (3) Bromazepam 2748
 (4) Camazepam 2749
 (5) Chloral betaine 2460
 (6) Chloral hydrate 2465
 (7) Chlordiazepoxide 2744
 (8) Clobazam 2751
 (9) Clonazepam 2737
 (10) Clorazepate 2768
 (11) Clotiazepam 2752
 (12) Cloxazolam 2753
 (13) Delorazepam 2754
 (14) Diazepam 2765
 (15) Estazolam 2756
 (16) Ethchlorvynol 2540
 (17) Ethinamate 2545
 (18) Ethyl loflazepate 2758
 (19) Fludiazepam 2759
 (20) Flunitrazepam 2763
 (21) Flurazepam 2767
 (22) Halazepam 2762

(23) Haloxazolam	2771
(24) Ketazolam	2772
(25) Loprazolam	2773
(26) Lorazepam	2885
(27) Lormetazepam	2774
(28) Mebutamate	2800
(29) Medazepam	2836
(30) Meprobamate	2820
(31) Methohexitol	2284
(32) Methylphenobarbital (mephobarbital)	2250
(33) Midazolam	2884
(34) Nimetazepam	2837
(35) Nitrazepam	2834
(36) Nordiazepam	2838
(37) Oxazepam	2835
(38) Oxazolam	2839
(39) Paraldehyde	2585
(40) Petrichloral	2591
(41) Phenobarbital	2285
(42) Pinazepam	2883
(43) Prazepam	2784
(44) Quazepam	2881
(45) Temazepam	2925
(46) Tetrazepam	2886
(47) Triazolam	2887
(48) Zaleplon	2781
(49) Zolpidem	2783

(d) *Fenfluramine.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

Fenfluramine 1670

(e) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Cathine ((+)-norpseudoephedrine) 1230
 (2) Diethylpropion 1610
 (3) Fencamfamin 1760
 (4) Fenproporex 1575
 (5) Mazindol 1805
 (6) Mefenorex 1580
 (7) Modafinil 1680
 (8) Pemoline (including organometallic complexes and chelates thereof) 1530
 (9) Phentermine 1640
 (10) Pipradrol 1750
 (11) Sibutramine 1675
 (12) SPA ((-)-1-dimethylamino- 1,2-diphenylethane) 1635

(f) *Other substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine 9709
 (2) Butorphanol (including its optical isomers) 9720

[39 FR 22143, June 20, 1974]

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1308.15 Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine 9064

(c) *Narcotic drugs containing non-narcotic active medicinal ingredients.* Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) *Stimulants.* Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect

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on the central nervous system, including its salts, isomers and salts of isomers:

(1) Pyrovalerone 1485.
(2) [Reserved]

[39 FR 22143, June 20, 1974, as amended at 43 FR 38383, Aug. 28, 1978; 44 FR 40888, July 13, 1979; 47 FR 49841, Nov. 3, 1982; 50 FR 8108, Feb. 28, 1985; 52 FR 5952, Feb. 27, 1987; 53 FR 10870, Apr. 4, 1988; 56 FR 61372, Dec. 3, 1991]

EXCLUDED NONNARCOTIC SUBSTANCES**§ 1308.21 Application for exclusion of a nonnarcotic substance.**

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g) (1) of the Act (21 U.S.C. 811 (g) (1)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(b) An application for an exclusion under this section shall contain the following information:

(1) The name and address of the applicant;
(2) The name of the substance for which exclusion is sought; and
(3) The complete quantitative composition of the substance.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it

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APPENDIX D: SUMMARY OF MENTAL HEALTH EXAMINATION

Summary

- The purpose of the examination is to identify health-related conditions that render an applicant *inadmissible* and conditions that will need follow-up care.
- Health-related conditions that render an applicant *inadmissible* are -
 - § Dependence on (addiction) or abuse of a specific substance provided in Schedule I-IV of Section 202 of the Controlled Substances Act.
 - § A physical or mental disorder (including alcohol-related disorders) that might cause or has caused harmful behavior.
 - § History of physical or mental disorder that has caused harmful behavior and is likely to recur.
- Mental disorders are characterized by alterations in thinking, mood, or behavior.
 - § Substance dependence and abuse are determined by DSM criteria.
 - Indicated medical use of a substance is not substance abuse.
 - § General mental disorders are determined by DSM criteria.
 - “V” coded conditions are not mental disorder diagnoses.
- Harmful behavior is -
 - § Serious psychological or physical injury to others or to the applicant.
 - § A serious threat to health or safety.
 - § Major damage to property.
- Harmful behavior alone (without mental or physical disorder) or a mental or physical disorder alone is not a health-related condition that renders an applicant inadmissible.
 - § Any antisocial act requires further investigation, but mental disorder diagnoses involve patterns of behavior, not single events.
- The classification (A or B) is used to determine admissibility and the need for follow-up care.
- Remission is determined by DSM criteria.
 - § Sustained, full remission for substance-related disorders is at least 12 months.
 - § Sustained, full remission is dependent on clinical judgment but requires reliable evidence.
 - § A statement signed by the applicant is helpful in documenting -
 - The applicant’s understanding of his or her condition, and
 - Requirements to demonstrate remission, such clinical reports.
- Harmful behavior unlikely to recur includes the following factors -
 - § Remission or control of the mental disorder for at least 12 months.
 - § External circumstances influencing that behavior have changed.
- The eligibility to apply for a waiver is determined by law. DHS, USCIS has the final authority to adjudicate the waiver request.

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