under the age of consent) and youth, conduct focus groups with youth with substance use and/or mental health conditions, and interview health care professionals who treat youth with these conditions. The screen will be administered by telephone to parents first and, as eligible, to youth and will take 10 minutes to complete for parents and for youth. Questions will include a mix of open-ended and closed-ended responses and are intended to gather information on previous diagnosis and symptomology of mental health conditions and availability to participate in the focus group. The focus groups with youth will be conducted in person and will take up to 90 minutes. Questions are primarily open-ended and intended to gather information on the reasons youth with substance use and/or mental health conditions use tobacco, the barriers and facilitators to tobacco use prevention and cessation, the appeal of various tobacco use prevention and cessation messages, and the best dissemination strategies and communication channels for a future campaign aimed at this specialized group. The interviews with health care professionals who treat youth with mental health and/or substance use conditions will be conducted in person, as feasible, or by telephone and will take up to 45 minutes. Questions are primarily open-ended and intended to gather information to better understand how various health care professionals screen for and address tobacco use in youth receiving care in their practice, identify messages and materials aimed at health care professionals to address tobacco use prevention and cessation in youth with substance use and/or mental health conditions, determine the most efficient communication strategies and channels to disseminate this information. All data collections are voluntary.

Below is the table of the estimated total burden hours:

Respondent	Number of respondents	Responses per respondent	Average burden hour	Total hour burden
Screener (Parent)	576	1	.15	86.4
Screener (Youth)	144	1	.15	21.6
Youth Focus Group	*108	1	1.50	162
Provider Interview	42	1	.75	31.5
Total	762			301.5

*The 108 respondents identified for the youth focus groups are included in the 144 respondents for the youth screener.

Written comments and recommendations concerning the proposed information collection should be sent by October 23, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2013–23053 Filed 9–20–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence (CFE) Screening and Brief Intervention (SBI) Project and Project CHOICES Evaluation (OMB No. 0930–0302)—Reinstatement

Since 2001, SAMHSA's Center for Substance Abuse Prevention has been operating the SAMHSA Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence (CFE). The purpose of the FASD Center for Excellence is to prevent alcohol-exposed pregnancies among women of childbearing age and pregnant women and to improve the quality of life for individuals affected by FASD. Data will be collected from women served across approximately 10 sites in local/community-based agencies. Women will be screened for alcohol use, and provided appropriate interventions based on their pregnancy status.

The FASD CFE will be integrating Screening and Brief Intervention (SBI) for pregnant women and Project CHOICES for non-pregnant women through service delivery organizations and will monitor the results. Approximately 10 sites will implement the SBI program and/or Project CHOICES.

At baseline, an assessment form will be administered by the counselor to screen women at the participating sites or health care delivery programs. Basic demographic data will be collected for all women screened (age, race/ethnicity, education, and marital status) at baseline by participating sites but no personal identification information will be transmitted to SAMHSA. Both quantity and frequency of drinking will be assessed for all women. Pregnant women will be assessed for risk of alcohol use using the TWEAK screening instrument, which has been used successfully with pregnant women. Non-pregnant women will be assessed for ability to conceive and use of effective birth control.

SBI focuses on 10- to 15-minute counseling sessions, conducted by a counselor who will use a scripted manual to guide the program. Participants in SBI will be assessed throughout their pregnancy to monitor

alcohol use, referred for additional services to support their efforts to stop drinking, and will be provided with the 10–15 minute program until the client abstains from alcohol. Clients will be followed up until their 36th week of pregnancy. At each process visit, the quantity and frequency of drinking will be assessed and the client's goals for drinking will be recorded. In addition, process level variables will be assessed to understand how the program is being implemented (e.g., whether SBI was delivered; duration of the program; what referrals were made; client satisfaction). At the 36th week of pregnancy quantity and frequency of drinking will be assessed, and the client's satisfaction with the program will be recorded.

For those who screen positive for Project CHOICES (non-pregnant women 18–44 years who are at risk for an alcohol-exposed pregnancy), the program will provide two Motivational Interviewing (MI) sessions related to alcohol use, plus one contraceptive counseling session. The goal is to help these women prevent an alcohol-exposed pregnancy by abstaining from alcohol and using contraceptive methods of their choice consistently and correctly. At the end of the Project CHOICES program, women are assessed on their alcohol consumption and contraceptive use in the past 30 days, and their satisfaction with the program is recorded. At 3 months and 6 months after the end of the program, women are assessed on 30-day alcohol consumption and contraceptive use using the same core assessment form that was used at baseline.

All participating sites will maintain personally identifiable information of their clients for service delivery purposes, but the sites will keep such information private to the maximum extent allowable by laws. Data will be collected at the site level and sites will be instructed to keep personal data secure in a specified location. To further ensure privacy of individual responses, all data will be reported at the aggregate level so that individual responses cannot be identified; no data will be reported at the individual participant level. Furthermore, data will be collected to meet the criteria of a ''limited data set'' as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (HIPAA), (HIPAA Privacy Rule, 45 CFR _164.501) [45 CFR 164.514(e)(4)(ii)]. A computer generated coding system will be used to identify the records, and access to records will be limited only to authorized personnel. In addition, the identifiers will be stored separately from the data. No direct identifiers will be included in order for the data to be considered a ''limited data set.'' A summary of the actions the contractors will take in order to comply with HIPAA follows:

- Ensure that the personal health information respondents disclose to outside entities does not violate the Privacy Rule.
- When creating a unique identification code, ensure that the code does not contain information that can be used to identify the individual.
- Sign a data agreement that states all HIPAA requirements will be adhered to consistent with a limited data set.
- Agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

The data collection is designed to monitor the implementation of the proposed programs by measuring whether abstinence from alcohol is achieved, and for Project CHOICES by measuring whether effective birth control practices are performed. Furthermore, the program will include process measures to monitor how the interventions were provided.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument/activity	Number of respondents	Number of responses per respondent	Total number of responses	Average burden per response	Total burden hours per collection
Pregnant Women (SBI)					
Baseline Assessment (Form A)	9,273	1	9,273	.25	2,318
Process Assessment for all Eligible women (Forms A and B) (26.6% of baseline)	2,468	2	4,936	.21	1,037
Process Assessment for women actively drinking (Forms A and B) (16% of 2,468 eligible women)	395	1	395	.21	83
End of Program Assessment (Forms A and C) (50% of eligible women)	1,234	1	1,234	.16	197
SBI Sub Total	9,273		15,838		3,635
Non-Pregnant Women (Project CHOICES)					
Baseline Assessment (Form A)	1,220	1	1,220	.25	305
End of program Assessment (Forms A and C) (50% of 629 eligible women)	314	1	314	.25	79
Follow-up Assessment (Form A) (50% of 629 eligible women)	314	2	628	.25	157
Project CHOICES Sub Total	1,220		2,162		541
Totals	10,493		18,000		4,176

Written comments and recommendations concerning the proposed information collection should be sent by October 23, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays

in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2013–0499]

Change-1 to Navigation and Inspection Circular 04–08

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of Change-1 to Navigation and Vessel Inspection Circular 04–08, ''Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials'' (NVIC 04–08). Change-1 to NVIC 04–08 contains a summary and clarification of Coast Guard policies regarding the criteria for granting medical waivers to merchant mariner credential applicants who have had either anti-tachycardia devices or implantable cardioverter defibrillators implanted, and to applicants who have had a seizure. This notice also addresses comments we received in response to Coast Guard notices published in the **Federal Register** on September 7, 2012, and March 25, 2013 soliciting public comments on these issues.

DATES: Change-1 to NVIC 04–08 is effective on September 23, 2013.

ADDRESSES: NVIC 04–08 is available in the docket and can be viewed by going to *http://www.regulations.gov* and using ''USCG–2013–0499'' as your search term. Locate this notice in the search results. NVIC 04–08 is available by clicking the ''Supporting Documents'' link. NVIC 04–08 is also available on the Coast Guard's Web site at: *www.uscg.mil/nmc.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Ashley Holm, Office of Commercial Vessel Compliance (CG–CVC), 202–372–1128, email *MMCPolicy@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

General Waiver Criteria

Coast Guard regulations in 46 CFR 10.215 contain the medical standards that merchant mariner applicants must meet prior to being issued a merchant mariner credential (MMC). In cases where the applicant does not meet the medical standards in 46 CFR 10.215, the Coast Guard may issue a waiver when extenuating circumstances exist that warrant special consideration (*see* 46 CFR 10.215(g)).

Anti-Tachycardia Devices and Implantable Cardioverter Defibrillators

Coast Guard guidance in NVIC 04–08 provides that anti-tachycardia devices and implantable cardioverter defibrillators (ICDs) are generally not waiverable. Prior to issuing Change-1 to NVIC 04–08, Coast Guard guidance did not identify waiver criteria associated with anti-tachycardia devices or ICDs, rendering it difficult for Coast Guard personnel to consistently evaluate merchant mariner applicants with anti-tachycardia devices or ICDs, and assess whether an applicant's medical condition warranted granting a medical waiver under 46 CFR 10.215(g). Enclosure (7) to NVIC 04–08 now provides guidelines to use when assessing an applicant's eligibility for a waiver.

On September 7, 2012 we published a notice in the **Federal Register** requesting public comments on this issue (77 FR 55174). On December 17, 2012, we re-opened and extended the public comment period for an additional 30 days to provide additional opportunity to comment (77 FR 74630). We summarize the policy in Enclosure (7) to NVIC 04–08 and address the public comments below.

Seizures

Coast Guard regulations in 46 CFR 10.215(d) state that a convulsive disorder (i.e., seizure disorder) could lead to an applicant's disqualification from receiving a credential. Prior to issuing Change-1 to NVIC 04–08, Coast Guard guidance did not identify waiver criteria associated with applicants that had a history of seizures rendering it difficult for Coast Guard personnel to consistently evaluate merchant mariner applicants with seizures and assess whether an applicant's medical condition warranted granting a medical waiver under 46 CFR 10.215(g). Enclosure (8) to NVIC 04–08 now provides guidelines to use when assessing an applicant's eligibility for a waiver.

On March 25, 2013 we published a notice in the **Federal Register** requesting public comments on this issue (78 FR 17917). We summarize the policies in Enclosure (8) to NVIC 04–08 and address the public comments below.

II. Discussion

ICD Policy

Prior to Change-1, NVIC 04–08 referred applicants to the Coast Guard's National Maritime Center (NMC) for guidance on the treatment of ICDs. ICDs were generally not waiverable. Enclosure (7) provides a list of criteria to be considered when evaluating an application from a mariner with an ICD. While the policy remains that ICDs are generally not waiverable, the criteria in Enclosure (7) will identify those limited situations where a waiver will be considered. The criteria that must be met to be considered for a waiver are:

(1) The applicant does not have a diagnosis of a cardiac channelopathy affecting the electrical conduction of the heart (to include Brugada syndrome, Long QT syndrome, etc.);

(2) The applicant does not have a prior history of ventricular fibrillation or episodes of sustained ventricular tachycardia within the last three years;

(3) The ICD or anti-tachycardia device was implanted more than three years ago;

(4) The ICD has not fired nor has the applicant required anti-tachycardia pacing therapy within the last three years;

(5) There are no additional risk factors for inappropriate shock such as uncontrolled atrial fibrillation;

(6) The applicant's left ventricular ejection fraction (EF) [1] is greater than 35% with a steady or improving trend;

(7) There is no history of any symptomatic or clinically significant heart failure in the past two years;

(8) There is no evidence of significant reversible ischemia on myocardial perfusion imaging exercise stress testing;

(9) The applicant's exercise capacity on formal stress testing (using standard

[1] The left ventricular ejection fraction measures the percentage of blood that the left ventricle of the heart is able to pump with each beat. A normal ejection fraction is greater than 50%.