Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2015–N–3785 for “Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the SECG entitled “Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Constance Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993–0002, 301–796–6951, Constance.Soves@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 1, 2019 (84 FR 12088), FDA issued a final rule to classify posterior cervical screw systems into class II (special controls) and to continue to require a premarket notification (510(k)) to provide a reasonable assurance of safety and effectiveness of the device (the final rule). The final rule, which is codified at 21 CFR 888.3075, became effective May 1, 2019.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), FDA is making this SECG available to explain the actions that a small entity must take to comply with the final rule.

This level 2 guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 807, subparts A through D, have been approved under OMB control number 0910–0625.

III. Electronic Access

Persons interested in obtaining a copy of the SECG may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This guidance document is also available at https://www.regulations.gov. Persons unable to download an electronic copy of “Classification of Posterior Cervical Screw Systems” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 20008 and complete title to identify the guidance you are requesting.

Date: April 24, 2020.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2020–09188 Filed 5–1–20; 8:45 am]

BILLING CODE 4164–01–P
Internal Revenue Service, Department of the Treasury.

**ACTION:** Notification of relief; extension of timeframes.

**SUMMARY:** This document announces the extension of certain timeframes under the Employee Retirement Income Security Act and the Internal Revenue Code for group health plans, disability and other welfare plans, pension plans, and participants and beneficiaries of these plans during the COVID–19 National Emergency.

**DATES:** May 4, 2020.

**FOR FURTHER INFORMATION CONTACT:**

**SUPPLEMENTARY INFORMATION:**

### I. Purpose

On March 13, 2020, President Trump issued the Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak and by separate letter made a determination, under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq., that a national emergency exists nationwide beginning March 1, 2020, as the result of the COVID–19 outbreak (the National Emergency). As a result of that determination, the Federal Emergency Management Agency (FEMA) issued emergency declarations for every state, territory, and possession of the United States.

As a result of the National Emergency, participants and beneficiaries covered by group health plans, disability or other employee welfare benefit plans, and employee pension benefit plans may encounter problems in exercising their health coverage portability and continuation coverage rights, or in filing or perfecting their benefit claims. Recognizing the numerous challenges participants and beneficiaries already face as a result of the National Emergency, it is important that the Employee Benefits Security Administration, Department of Labor, Internal Revenue Service, and Department of the Treasury (the Agencies) take steps to minimize the possibility of individuals losing benefits because of a failure to comply with certain pre-established timeframes. Similarly, the Agencies recognize that affected group health plans may have difficulty in complying with certain notice obligations.

Accordingly, under the authority of section 518 of the Employee Retirement Income Security Act of 1974 (ERISA) and section 7508A(b) of the Internal Revenue Code of 1986 (the Code), the Agencies are extending certain timeframes otherwise applicable to group health plans, disability and other welfare plans, pension plans, and their participants and beneficiaries under ERISA and the Code. The Agencies believe that such relief is immediately needed to preserve and protect the benefits of participants and beneficiaries in all employee benefit plans across the United States during the National Emergency. Accordingly, the Agencies have determined, pursuant to section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A), (B) and 553(d), that there is good cause for granting the relief provided by this document effective immediately upon publication, and notice and public participation may result in undue delay and, therefore, be contrary to the public interest.


**II. Background**

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides portability of health coverage by, among other things, result of the COVID–19 pandemic, and the same reasons underlying the issuance of the January 31, 2020 declaration that a public health emergency exists under section 319 of the Public Health Service Act (PHS Act).

Section 104 of the Title I of Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that the Secretaries of Labor, the Treasury, and Health and Human Services (the Departments) ensure through an interagency Memorandum of Understanding (MOU) that regulations, rulings, and interpretations issued by each of the Departments relating to the same matter over which two or more departments have jurisdiction, are administered so as to have the same effect at all times. Under section 104, the Departments, through the MOU, are to provide for coordination of policies relating to enforcement of the same requirements in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priority to enforcement. See section 104 of HIPAA and Memorandum of Understanding applicable to Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code, published at 64 FR 70164, December 15, 1999.
requiring special enrollment rights into group health plans upon the loss of eligibility of coverage. ERISA section 701, Code section 9801, 29 CFR 2590.701–6, 26 CFR 54.9801–6. Title X of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) permits qualified beneficiaries who lose coverage under a group health plan to elect continuation health coverage. ERISA section 601, Code section 4980B, 26 CFR 54.4980B–1. Section 503 of ERISA and 29 CFR 2560.503–1 require employee benefit plans subject to Title I of ERISA to establish and maintain reasonable procedures governing the determination and appeal of claims for benefits under the plan. Section 2719 of the PHS Act, incorporated into ERISA by ERISA section 715, and into the Code by Code section 9815, imposes additional rights and obligations with respect to internal claims and appeals and external review for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. See also 29 CFR 2590.715–2719 and 26 CFR 54.9815–2719. All of the foregoing provisions include timing requirements for certain acts in connection with employee benefit plans, some of which are being modified by this document.

A. Special Enrollment Timeframes

In general, HIPAA requires a special enrollment period in certain circumstances, including when an employee or dependent loses eligibility for any group health plan or other health insurance coverage in which the employee or the employee’s dependents were previously enrolled (including coverage under Medicaid and the Children’s Health Insurance Program), and when a person becomes a dependent of an eligible employee by birth, marriage, adoption, or placement for adoption. ERISA section 701(f), Code section 9801(f), 29 CFR 2590.701–6, and 26 CFR 54.9801–6. Generally, group health plans must allow such individuals to enroll in the group health plan at insured eligible and if enrollment is requested within 30 days of the occurrence of the event (or within 60 days, in the case of the special enrollment rights added by the Children’s Health Insurance Program Reauthorization Act of 2009). ERISA section 701(f), Code section 9801(f), 29 CFR 2590.701–6, and 26 CFR 54.9801–6.

B. COBRA Timeframes

The COBRA continuation coverage provisions generally provide a qualified beneficiary a period of at least 60 days to elect COBRA continuation coverage under a group health plan. ERISA section 605 and Code section 4980B(f)(5). Plans are required to allow payment of premiums in monthly installments, and plans cannot require payment of premiums before 45 days after the day of the initial COBRA election. ERISA section 602(3) and Code section 4980B(f)(2)(C). COBRA continuation coverage may be terminated for failure to pay premiums timely. ERISA section 602(2)(C) and Code section 4980B(f)(2)(B)(iii). Under the COBRA rules, a premium is considered paid timely if it is made not later than 30 days after the first day of the period for which payment is being made. ERISA section 602(2)(C), Code section 4980B(f)(2)(B)(ii), and 26 CFR 54.9800B–8 Q&A–5(a). Notice requirements prescribe time periods for employers to notify the plan of certain qualifying events and for individuals to notify the plan of certain qualifying events or a determination of disability. Notice requirements also prescribe a time period for plans to notify qualified beneficiaries of their rights to elect COBRA continuation coverage. ERISA section 606, Code section 4980B(f)(6), and 29 CFR 2590.606–3.

C. Claims Procedure Timeframes

Section 503 of ERISA and 29 CFR 2560.503–1, as well as section 2719 of the PHS Act, incorporated into ERISA by ERISA section 715 and 29 CFR 2590.715–2719, and into the Code by Code section 9815 and 26 CFR 54.9815–2719, require ERISA-covered employee benefit plans and non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to establish and maintain a procedure governing the filing and initial disposition of benefit claims, and to provide claimants with a reasonable opportunity to appeal an adverse benefit determination to an appropriate named fiduciary. Plans may not have provisions that unduly inhibit or hamper the initiation or processing of claims for either group health plans and disability plans must provide claimants at least 180 days following receipt of an adverse benefit determination to appeal (60 days in the case of pension plans and other welfare benefit plans). 29 CFR 2560.503–1(h)(2)(i) and (h)(3)(i), 29 CFR 2590.715–2719(b)(2)(ii)(C), and 26 CFR 54.9815–2719(b)(2)(ii)(C).

D. External Review Process Timeframes

PHS Act section 2719, incorporated into ERISA by ERISA section 715 and into the Code by Code section 9815, sets out standards for external review that apply to non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage and provides for either a State external review process or a Federal external review process. Standards for external review processes and timeframes for submitting claims to the independent reviewer for group health plans or health insurance issuers may vary depending on whether a plan uses a State or Federal external review process. The Federal external review process also provides for a preliminary review of a request for external review. The regulation provides that if such request is not complete, the Federal external review process must provide for a notification that describes the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48-hour period following the receipt of the notification, whichever is later. 29 CFR 2590.715–2719(d)(2)(i) and 26 CFR 54.9815–2719(d)(2)(i). The Federal external review process also provides for a preliminary review of a request for external review. The regulation provides that if such request is not complete, the Federal external review process must provide for a notification that describes the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48-hour period following the receipt of the notification, whichever is later. 29 CFR 2590.715–2719(d)(2)(i) and 26 CFR 54.9815–2719(d)(2)(i).

III. Relief

A. Relief for Plan Participants, Beneficiaries, Qualified Beneficiaries, and Claimants

Subject to the statutory duration limitation in ERISA section 518 and Code section 7508A, all group health plans, disability and other employee welfare benefit plans, and employee pension benefit plans subject to ERISA or the Code must disregard the period from March 1, 2020 until sixty (60) days after the announced end of the National Emergency or such other date announced by the Agencies in a future notification (the “Outbreak Period”) for all plan participants, beneficiaries, qualified beneficiaries, or claimants wherever located in determining the following periods and dates—

1. The 30-day period (or 60-day period, if applicable) to request special enrollment under ERISA section 701(f) and Code section 9801(f),

2. See footnote 4, supra.

8 To the extent there are different Outbreak Period end dates for different parts of the country, the Agencies will issue additional guidance regarding the application of the relief in this document.
IV. Examples

The following examples illustrate the timeframe for extensions required by this document. An assumed end date for the National Emergency was needed to make the examples clear and understandable. Accordingly, the Examples assume that the National Emergency ends on April 30, 2020, with the Outbreak Period ending on June 29, 2020 (the 60th day after the end of the National Emergency). To the extent there are different Outbreak Period end dates for different parts of the country, the Agencies will issue additional guidance regarding the application of the relief in this document.

Example 1 (E lecting COBRA). (i) Facts. Individual A works for Employer X and participates in X’s group health plan. Due to the National Emergency, Individual A experiences a qualifying event for COBRA purposes as a result of a reduction of hours below the hours necessary to meet the group health plan’s eligibility requirements and has no other coverage. Individual A is provided a COBRA election notice on April 1, 2020. What is the deadline for A to elect COBRA?

(ii) Conclusion. In Example 1, Individual A is eligible to elect COBRA coverage under Employer X’s plan. The Outbreak Period is disregarded for purposes of determining Individual A’s COBRA election period. The last day of Individual A’s COBRA election period is 60 days after June 29, 2020, which is August 28, 2020.

Example 2 (Special enrollment period). (i) Facts. Individual B is eligible for, but previously declined participation in, her employer-sponsored group health plan. On March 31, 2020, Individual B gave birth and would like to enroll herself and her child into her employer’s plan; however, open enrollment does not begin until November 15. When may Individual B exercise her special enrollment rights?

(ii) Conclusion. In Example 2, the Outbreak Period is disregarded for purposes of determining Individual B’s special enrollment period. Individual B and her child qualify for special enrollment into her employer’s plan as early as the date of the child’s birth. Individual B may exercise her special enrollment rights for herself and her child into her employer’s plan until 30 days after June 29, 2020, which is July 29, 2020, provided that she pays the premiums for any period of coverage.

Example 3 (COBRA premium payments). (i) Facts. On March 1, 2020, Individual C was receiving COBRA continuation coverage under a group health plan. More than 45 days had passed since Individual C had elected COBRA. Monthly premium payments are due by the first of the month. The plan does not permit qualified beneficiaries longer than the statutory 30-day grace period for making premium payments. Individual C made a timely February payment, but did not make the March payment or any subsequent payments during the Outbreak Period. As of July 1, Individual C has made no premium payments for March, April, May, or June. Does Individual C lose COBRA coverage, and if so for which month(s)?

(ii) Conclusion. In Example 3, the Outbreak Period is disregarded for purposes of determining whether monthly COBRA premium installment payments are timely. Premium payments made by 30 days after June 29, 2020, which is July 29, 2020, for March, April, May, and June 2020, are timely, and Individual C is entitled to COBRA continuation coverage for these months if she timely makes payment. Under the terms of the COBRA statute, premium payments are timely if made within 30 days from the date they are first due. In calculating the 30-day period, however, the Outbreak Period is disregarded, and payments for March, April, May, and June are all deemed to be timely if they are made within 30 days after the end of the Outbreak Period. Accordingly, premium payments for four months (i.e., March, April, May, and June) are all due by July 29, 2020. Individual C is entitled to continue coverage under the terms of the plan during this interim period even though some or all of Individual C’s premium payments may not be received until July 29, 2020. Since the due dates for Individual C’s premiums would be postponed and Individual C’s payment for premiums would be retroactive during the initial COBRA election period, Individual C’s insurer or plan may not deny coverage, and may make retroactive payments for benefits and services received by the participant during this time.

Example 4 (COBRA premium payments). (i) Facts. Same facts as Example 3. By July 29, 2020, Individual C made a payment equal to two months’ premiums. For how long does Individual C have COBRA continuation coverage?

(ii) Conclusion. Individual C is entitled to COBRA continuation coverage for March and April of 2020, the two months for which timely premium payments were made, and Individual C is not entitled to COBRA continuation coverage for any month after April 2020. Benefits and services
provided by the group health plan (e.g.,
doctors’ visits or filled prescriptions)
that occurred on or before April 30,
2020 would be covered under the
terms of the plan. The plan would not be
obligated to cover benefits or services
that occurred after April 2020.

Example 5 (Claims for medical
treatment under a group health plan). (i) 
Facts. Individual D is a participant in a
group health plan. On March 1, 2020,
Individual D received medical treatment
for a condition covered under the plan,
but a claim relating to the medical
treatment was not submitted until April
1, 2021. Under the plan, claims must be
submitted within 365 days of the
participant’s receipt of the medical
treatment. Was Individual D’s claim
timely?

(ii) Conclusion. Yes. For purposes of
determining the 365-day period
applicable to Individual D’s claim, the
Outbreak Period is disregarded.

Therefore, Individual D’s last day to
submit a claim is 365 days after June 29,
2020, which is June 29, 2021, so
Individual D’s claim was timely.

Example 6 (Internal appeal—
disability plan). (i) Facts. Individual E
received a notification of an adverse
The notification advised Individual E
that there are 180 days within which to
file an appeal. What is Individual E’s
appeal deadline?

(ii) Conclusion. When determining the
180-day period within which Individual E’s appeal must be filed, the Outbreak
Period is disregarded. Therefore,
Individual E’s last day to submit an
appeal is 148 days (180 – 32 days
following January 28 to March 1) after
June 29, 2020, which is November 24,
2020.

Example 7 (Internal appeal—
employee pension benefit plan). (i) 
Facts. Individual F received a notice of
adverse benefit determination from
Individual F’s 401(k) plan on April 15,
2020. The notification advised
Individual F that there are 60 days
within which to file an appeal. What is
Individual F’s appeal deadline?

(ii) Conclusion. When determining the
60-day period within which Individual F’s appeal must be filed, the Outbreak
Period is disregarded. Therefore,
Individual F’s last day to submit an
appeal is 60 days after June 29, 2020,
which is August 28, 2020.

Signed at Washington, DC, this 28th day of
April, 2020.

Eugene Rutledge,
Assistant Secretary, Employee Benefits
Security Administration, Department of
Labor.

Sunita Lough,
Deputy Commissioner for Services and
Enforcement, Internal Revenue Service,
Department of the Treasury.

[FR Doc. 2020–09399 Filed 4–30–20; 11:15 am]

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

Double Coverage

AGENCY: Office of the Secretary, 
Department of Defense (DoD).

ACTION: Technical amendment.

SUMMARY: This technical amendment
is being published to correct an error that
was codified in the Code of Federal
Regulations (CFR) in 2003. A paragraph
was inadvertently duplicated in 2003
and is now being removed.

DATES: This technical amendment is

FOR FURTHER INFORMATION CONTACT:
Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: On April
30, 2003 (68 FR 23030–23034), the
Department of Defense published a final
rule titled “TRICARE Program:
Eligibility and Payment Procedures for
Civilian Health and Medical Program of
the Uniformed Services Beneficiaries
Age 65 and Over,” which amended 32
CFR part 199.

On page 23032, an amendatory
instruction requested to amend § 199.8
by “redesignating paragraph (c)(5) as
(c)(6) and the second paragraph (c)(4) as
(c)(5).”

The wording of this amendatory
instruction led to a codification error
which is still present in the CFR.

In 32 CFR 199.8, paragraphs (c)(5) and
(c)(6) contain identical text. Only one of
the paragraphs should remain in the
CFR. Therefore, DoD is publishing this
technical amendment to remove
paragraph (c)(6) from 32 CFR 199.8.

It has been determined that
publication of this CFR amendment for
public comment is impracticable,
unnecessary, and contrary to public
interest since it is correcting a technical
error.

This rule is not significant under
Executive Order (E.O.) 12866,
“Regulatory Planning and Review.”
Therefore, E.O. 13771, “Reducing
Regulation and Controlling Regulatory
Costs,” does not apply.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care,
Health insurance, Individuals with
disabilities, Mental health, Mental
health parity, Military personnel.

Accordingly, 32 CFR part 199 is
amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199
continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter
55.

§ 199.8 [Amended]

2. Amend § 199.8 by removing
paragraph (c)(6).


Aaron T. Siegel,
Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2020–08664 Filed 5–1–20; 8:45 am]

DEPARTMENT OF HOMELAND
SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0084]

RIN 1625–AA08

Special Local Regulation; Tred Avon
River, Between Bellevue and Oxford,
MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is
establishing temporary special local
regulations for certain waters of the Tred
Avon River. This action is
necessary to provide for the safety of life
on these navigable waters located
between Bellevue, MD, and Oxford, MD,
during a swim event on June 6, 2020.

This regulation prohibits persons and
vessels from entering the regulated area
unless authorized by the Captain of the
Port Maryland-National Capital Region
or the Coast Guard Patrol Commander.

DATES: This rule is effective from 6:45
a.m. to 10:15 a.m. on June 6, 2020.

ADDRESSES: To view documents
mentioned in this preamble as being
available in the docket, go to https://
www.regulations.gov, type USCG–2020–
0084 in the “SEARCH” box and click
“SEARCH.” Click on Open Docket
Folder on the line associated with this
rule.