human factors study that demonstrates that an intended user can safely use the device for its intended use.

(7) Device labeling must include the following:

(i) A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate.

(ii) A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.

(iii) A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: Number of bolus doses with volume that is <25 percent, 25 percent to <75 percent, 75 percent to <95 percent, 95 percent to <105 percent, 105 percent to <125 percent, 125 percent to <175 percent, 175 to 250 percent, and >250 percent of the commanded amount.

(iv) A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warmup period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on the drug delivered) may be provided as follows, as applicable: The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point.

(v) A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps.

(vi) For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.

(vii) For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02369 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ97

Informed Consent and Advance Directives

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) published an interim final rule amending its regulation regarding informed consent and advance directives. In that rulemaking, we amended the regulation by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. Before adopting that interim final rule as final, VA revises the provision related to which personnel may be delegated the responsibility for providing a patient with information needed for the patient to make a fully informed consent decision. Upon further review, VA has determined that this provision requires a further change to better clarify roles in the team-based delivery of care model. We are providing the public an opportunity to submit comments solely on this amendment.

DATES:

Effective date: This interim final rule is effective February 4, 2022.

Comments due date: Comments must be received on or before April 5, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Lucinda Potter, LSW, Acting Director of Ethics Policy, National Center for Ethics in Health Care (10ETH), Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; 484–678–5150. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In an interim final rule published May 27, 2020 (85 FR 31690), we amended 38 CFR 17.32, our regulation addressing informed consent for treatments and procedures, by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witnessing for a VA Advance Directive. We amended the definition of ''practitioner'' to include other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

Under the previous informed consent rule, the practitioner, who had primary responsibility for the patient or who would perform the particular procedure or provide the treatment, was responsible for explaining in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. There was no provision in the rule addressing the question of whether, consistent with a team-based delivery of care model, appropriately trained health care team members had a role in the informed consent process. In the May 2020 interim final rule, we dealt with that issue in paragraph (c)(6), stating that the practitioner may delegate to other trained personnel responsibility for providing the patient with clinical information needed for the patient to make a fully informed consent decision but must personally verify with the patient that the patient has been appropriately informed and voluntarily consents to the treatment or procedure.

VA intended that paragraph (c)(6) give the practitioner discretion to more fully utilize the training and expertise of non-practitioners within the bounds of the

team-based care model. Upon further review, VA has determined that this paragraph should be amended to more clearly reflect VA's intent to utilize a team-based approach for other elements of informed consent discussions in addition to provision of information to the patient. Consistent with longstanding VA policy and practice, we amend paragraph (c)(6) to more broadly state that trained personnel may conduct elements of the informed consent process when delegated by the practitioner.

We are also removing the term ''clinical information'' in this paragraph. We believe the term ''clinical information'' in the current paragraph (c)(6) could be problematic. It is not defined in VA regulations and is used only in VA policy documents either generically (to describe any health information reflected in medical records) or to describe specific types of stored information such as medical-related data, images, sound, and video related to certain types of medical examinations. ''Clinical information'' could also be narrowly used to describe only technical information related to a treatment or procedure. A narrow construction and application of that term is counter to the team model which is intended to benefit the patient by allowing members of the health care team to provide necessary information through different perspectives. This model also provides the patient an opportunity to freely communicate with not only the practitioner but also with other team members regarding the proposed treatment or procedure.

Based on that rationale, we amend paragraph (c)(6) to clarify that the practitioner may delegate to trained personnel the responsibility of conducting elements of the informed consent process beyond simply providing information. To ensure that clinical oversight is retained, the practitioner remains responsible for the informed consent process and must personally verify with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure. Elements of the informed consent process that may be delegated to trained personnel include providing patient education regarding the proposed treatment or procedure, identifying the authorized surrogate for patients who lack decision-making capacity, and assisting with obtaining the patient's (or surrogate's) signature for treatments and procedures that require signature informed consent.

VA believes that this will ensure that elements of informed consent discussions that may be appropriately delegated by providers are not unduly limited by regulation, while still making clear that the practitioner remains responsible for the informed consent process and for personally verifying with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure.

We are providing a 60-day period for submission of comments from the public on this amendment of § 17.32(c)(6). We are not accepting any public comment on any other content in § 17.32. Following the 60-day public comment period, we will review and consider comments received and then publish a final rulemaking capturing not only this interim final rule but also the May 2020 interim final rule.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B), to publish this amendment as an interim final rule without prior notice and the opportunity for public comment, and under 5 U.S.C. 553(d)(3), to dispense with the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).

Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' The Secretary finds that it is impractical to delay issuance of this rule for the purpose of soliciting prior public comment because there is an immediate and pressing need for VA to respond to the current public health crisis and national emergency by ensuring effective use of health care resources as part of the announced VA contingent/crisis standards of care, in addition to regular standards of care provided to eligible beneficiaries. VA believes members of a VA health care team should be utilized to the fullest extent practicable in providing veterans information on risks and benefits of proposed treatments or procedures. Thus, delaying the implementation of this clarifying amendment would be contrary to the public interest.

For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be both impracticable and contrary to the public interest. Accordingly, VA issues this amendment as a separate interim final rule. The Secretary will consider and address comments that are received within 60 days after the date that this interim final rule is published in the **Federal Register** and address them in a subsequent **Federal Register** document announcing a final rule incorporating any changes made in response to the public comments on this interim final rule and the May 2020 interim final rule.

The APA also requires a 30-day delayed effective date, except for ''(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.'' 5 U.S.C. 553(d). For the reasons stated above, the Secretary finds that there is also good cause for this interim rule to be effective immediately upon publication. It is in the public interest for VA to immediately adopt the process changes noted above to provide for effective utilization of VA practitioners as it relates to the informed consent process during this period of increased demand for health care, to provide flexibility to utilize alternative modalities of communications during the COVID–19 National Emergency, and to facilitate veterans documenting treatment preferences in an advance directive. By immediately making necessary process changes, the Secretary finds good cause to exempt this amendment from the APA's delayed effective date requirement.

Paperwork Reduction Act

Although this action contains provisions constituting collections of information, at 38 CFR 17.32, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this interim final rule. The information collection requirements for § 17.32 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0556.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612, because it affects only the informed consent process and use of advance directives within the VA health care system.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The amendment issued here as an interim final rule will not result in the expenditure of $100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Assistance Listing

The Assistance Listing program numbers and titles for the programs affected by this document are 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.012—Veterans Prescription Service; 64.013—Veterans Prosthetic Appliances; 64.014—Veterans State Domiciliary Care; 64.015—Veterans State Nursing Home Care; 64.024—VA Homeless Providers Grant and Per Diem Program; 64.026—Veterans State Adult Day Health Care; 64.029—Purchase Care Program; 64.039—CHAMPVA; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.044—VHA Home Care; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.049—VHA Community Living Center; 64.050—VHA Diagnostic Care; 64.054—Research and Development.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on January 31, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.32 by revising paragraph (c)(6) to read as follows:

§ 17.32 Informed consent and advance directives.

* * * * *

(c) * * *

(6) Trained personnel may conduct elements of the informed consent process when delegated by the practitioner. However, the practitioner remains responsible for the informed consent process and must personally verify with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure.

* * * * *

[FR Doc. 2022–02316 Filed 2–3–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

Clarification Concerning Tuition and Fees Payment Plans for Standard Terms and 85/15 Calculations

AGENCY: Department of Veterans Affairs.

ACTION: Policy interpretation.

SUMMARY: The Department of Veterans Affairs (VA) provides notice of a policy advisory issued on August 31, 2021, by VA's Education Service. The policy advisory clarifies and amends VA's previous regulatory interpretation of tuition and fees (T&F) payment plans to differentiate between types of payment plans. Some payment plans should no longer be categorized as institutional support to a student when calculating the ratio of ''supported'' to ''non-supported'' students in a program pursuant to the 85/15 Rule. While VA is retaining the general rule that a student who has a payment plan with an Educational Training Institute (ETI) should be considered supported, a student participating in a payment plan that meets the criteria set forth in this notice should *not* be considered supported and, instead, should be counted on the non-supported side of the 85/15 ratio.

DATES: This policy interpretation is applicable from February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Cheryl Amitay, Chief of Policy and Regulations Team, Education Service (225), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, Telephone: 202–461–9800 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The 85/15 rule (38 U.S.C. 3680A(d); 38 CFR 21.4201(a)) prohibits VA from paying educational assistance benefits to any new students once ''more than 85 percent of the students enrolled in the [program of education] are having all or part of their tuition, fees or other charges paid to or for them by the educational institution or by the Department of Veterans Affairs'' (38 U.S.C. 3680A(d)(1)). VA refers to students who receive such institutional or VA aid as ''supported'' students. Conversely, no less than 15 percent of the students enrolled in the program must be attending without having any of their tuition, fees or other charges paid to or for them by the educational institution or VA (referred to as non-supported students).

Currently, in accordance with 38 CFR 21.4201, educational institutions are