DH, MMRegulations

From: Tina Brunetti <tinambrunetti@gmail.com>
Sent: Sunday, April 4, 2021 9:55 PM
To: DH, MMRegulations; Collins, John; Senior, Holli
Cc: Lauren Vrabel; Mike Butler; Marci Lee; Natalie Capozzolo; sara.trimmer2003; mlrwerkheiser@gmail.com; Marcia McCarroll; Tammy Royer; Elizabeth H.; Annie Conner; Becky McCaskey; Richard Greer; Tina Brunetti
Subject: [External] 2021 PUBLIC FORUM Comments on Proposed Rulemaking [28 PA.CODE CHS.1131-1230 AND 1141a-1230a]
Attachments: Final Public Forum.1 - Rules and Regs - Comments 4.3.21.pdf

Dear John,

Thank you for taking the time to read and review the Pharmacists Advisory Board's comments on the Public Forum regarding the DOH's Proposed Rulemaking for the Pennsylvania Medical Marijuana Program (PAMMP). As a group of pharmacists actively working in the PAMMP, we have provided comments and questions where we feel clarification, improvement, and patient safety is warranted. We appreciate the opportunity to make an impact on the permanent regulations.

After reviewing the Proposed Rulemaking document, we feel it is even more important for the PAMMP to acknowledge and execute a Medical Professional Workgroup to collaborate with the Physician Workgroup and the Patient/Caregiver Workgroup.

Imagine what we can accomplish working together for the Program.

Best regards,

Pharmacists Advisory Board
PAMMP

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Code	Text	Comment
§ 1141a.48. Training	(a) As required by the Act, the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or physically handle seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products shall complete a 2-hour training course developed by the Department. This proposed section further provides that the Department will make its training course available at no cost to medical marijuana organizations, and medical marijuana organizations must retain the attendance records for the training and make them available to the Department upon request.	Amend to include these individuals are required to complete a 2-hour training course every **two** years. Consider changing wording to "course approved by the Department" OR "course developed and approved by the Department" and allow for submission of training courses and continuing education by parties deemed eligible by the Department. Comment: When flower was approved to purchase and when additional conditions were included to the list of qualifications, the approved training information did not reflect this update. "TRAIN" training and others may need to be updated on a regular basis. Comment: "attendance records" usually implies in-person training.
§ 1151a.24. Start-up inventory.	(a) A grower/processor may obtain seeds from outside of this Commonwealth for the purpose of securing its start-up inventory. Seeds obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational or within any 30-day window established by the Department if the Department determines that the importation of additional seeds is necessary. (b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time. (c) Within 24 hours of receipt, a grower/processor shall, record in the	Amend to allow a periodic window, every **five** years or as the Department deems necessary, to obtain seeds outside of this Commonwealth to ensure that grower/processors are able to continue to provide quality products for patients.

	electronic tracking system each seed that enters the site during the 30-day period under subsection (a). (d) Outside any 30-day period permitted under subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.	

§ 1151a.28. Forms of medical marijuana.	(a) A grower/processor may only process medical marijuana for dispensing to a patient or caregiver in the following forms: (1) Pill. (2) Oil. (3) Topical forms, including gel, creams or ointments. (4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization. (5) Tincture. (6) Liquid. (b) A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.	Amend to use appropriate nomenclature of products dispensed within the program. (1) Change 'Pill' to Oral Capsule, Tablet (2) Change 'Oil' to refer to RSO (Rick Simpson Oil) or similar Oral Syringe Preparations (3) Change 'Topical Forms' to include not only gel, creams, or ointments, but salves lotions, or any other topically administered product. (4) Change 'Tincture' to Oral Liquid, including solutions, suspension, or tinctures (5) Remove 'Liquid' unless not addressed by terminology above (6) Include 'Suppositories' or 'Rectal Formulations' (7) Include 'Flower' which includes all forms of dry leaf. (8) Include 'Edible' products and allow grower/processors to develop pre-dosed edibles including gummies, chocolate, and beverages to aid in the absorption of cannabinoids. Generally speaking, it is safer for the dosage to be prepared and fixed rather than to assume that patients are capable of preparing the correct dose for themselves. Amend to include (c) The Department will notify certifying physicians and medical professionals employed by dispensaries of any additionally approved dosage formulations as they are approved.

§ 1151a.34. Packaging and labeling of medical marijuana products.	(a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the Department or by a dispensary that purchased the medical marijuana products. (b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that is: (1) Child-resistant. (2) Tamper-proof or tamper-evident. (3) Opaque. (4) Resealable. (c) A grower/processor shall identify each process lot of medical marijuana with a unique identifier. (d) A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements: (1) Be easily readable. (2) Be made of weather-resistant and tamper-resistant materials. (3) Be conspicuously placed on the package. (4) Include the name, address and permit number of the grower/processor. (5) List the form, quantity and weight of medical marijuana included in the package. (6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages. CAS numbers need not be displayed on the label. (7) Contain an identifier that is unique to a particular harvest batch of	Amend (b) to include: (5) Differs in appearance to medical marijuana products of the same dosage formulation from the same grower/processor. Reason: Look-alike packaging risks dispensing the wrong product to patients which may lead to a serious adverse event. https://drive.google.com/file/d/1uk0ILkBpM4crcAjoxk7-ICYig6Uqx37-/view?usp=sharing (6) If anticipated weight and strength of product vary from the actual medical weight or strength, the grower/processor must indicate the variance in the labeling. Amend (d)(6) to indicate that THC and CBD and other cannabinoid quantities should be indicated per **mg** dose of infused edible products (as opposed to percentages). -OR- Amend (d)(6) to omit "(List) the number of individual doses contained within the package…" Reason: Each patient is different and may take more or less than what is recommended on the package. -OR- Amend (d)(6) to change "corresponding percentages" to "corresponding **mgs**." Please review the University of the Science's Medical Cannabis Labeling Recommendations, July 2019, *attached*. MedicalCannabisLabelingRecommendations.SUDI.July2019 **Look-alike packaging increases the risk of dispensing the incorrect product which may lead to unnecessary adverse events.

	medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch. (8) Include the date the medical marijuana product was packaged. (9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product. (10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9). (11) Contain the name and address of the dispensary to which the package is to be sold. (12) List the date of expiration of the medical marijuana product. (13) Include instructions for proper storage of the medical marijuana product in the package. (14) Contain the following warning stating: This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children. (15) Contain a warning that the medical marijuana product must be kept in the original container in which it was dispensed. (16) Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties. (17) Be firmly affixed to the container directly holding medical marijuana and be firmly affixed to outer packaging if used. (18) List THC as the first number when THC and CBD are listed on a label as a ratio.	Recommend: Barcodes applied to labels must be readable and functional by standard operating equipment; this includes placing the barcode in an appropriate location. For example, barcodes that are bent or placed around the curve of a container may not be readable and therefore product fulfillment in MJ Freeway needs to occur manually. Manually fulfilling products leaves room for error in dispensing, as multiple products may exist with Look-Alike, Sound-Alike (LASA) names, or several batches of the same product name may be available in active inventory. (18) Consider a generalization of cannabinoids other than CBD here as some products are beginning to come to market that also contain a predominance of cannabinoids other then CBD, i.e. Dr. Solomon's Doze Drops (CBN/THC), FRx Delta-8 products. -AND/OR- Amend (18) to state that cannabinoids other than THC and CBD will be listed first when THC and other predominant cannabinoids are listed on a label as a ratio. Reason: It is generally assumed that THC is dominant in a product unless identified in a ratio. Typically, the more dominant cannabinoid is presented first in the ratio therefore, if it is not THC, other predominant cannabinoids should be listed first. Comment: There are tinctures and oral solutions that only label the carton/outer packaging and the containers (bottles) are unlabeled. It will be safer for patients that often discard the cartons to know the

	Subsection (d). This proposed subsection requires that all packaging and labeling be approved by the Department and sets out the information that must be included on each label. The Department proposes to expand upon the requirements in the current subsection (d) by: (1) requiring that all packaging receive prior written approval of the Department; (2) requiring labels to list the species and percentages of all cannabinoids and individual terpenes; (3) requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging; and (4) requiring that THC be the first number in a THC:CBD ratio, when the labeling includes a ratio. These revisions minimize patient confusion caused by medical marijuana packaging, and also ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary. This proposed subsection otherwise mirrors the current subsection (d), except for technical revision to subsection (d)(2) to correct syntax.	mg/mL of each cannabinoid and terpenes and the final labeling on the container should indicate this. Comment: The standardization of the ratio expression is a step in the direction of simplifying the labels to improve the ability of the patient to understand what he/she is taking. There will be push back here since we have growers in PA listing the ratio in various ways. Comment: In the realm of prescription medications, we know that health care professionals struggle with calculating doses in general and especially when the math involves ratios and percentages to express concentration, and this has not been standardized yet. Many people in our program do not understand that 1:1 does not mean weak or strong and that 8:1 does not mean it is stronger than 1:1. In the examples of epinephrine (and other medications), we have many medication error reports that resulted in the phasing out of the expression of concentration at the level of the USP as a ratio to decrease confusion in 2016. The USP is the standard setting organization for the pharmaceutical industry. At this time our growers are individually listing a dose volume on the labels of the cartons and this is also not standardized. Some growers list one dose is 0.5 mL and others use 0.25 mL. If we select one standard way of expressing the concentration

		in terms of mg/mL, that may be the safest option moving forward. https://www.usp.org/health-quality-safety/medication-safety-labeling/elimination-ratio-expression single-entity-drug-labels Comment: Instead of discussing which cannabinoid to list first in the ratios, another option would be to list the mg/mL of each cannabinoid and mg/total bottle size of each cannabinoid to make that information as clear as possible for those that need to interpret the information for dosing.
1151a.35. Transportation of medical marijuana.	(a) A grower/processor may transport and deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following requirements apply: (1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory only between 7 a.m. and 9 p.m.	Amend (a)(1) to indicate that deliveries must be scheduled ahead of time and a representative at the organization must be notified prior to delivery. Deliveries must be coordinated at the dispensary level in order to ensure that multiple deliveries do not conflict or overlap. Consider implementing a scheduling system to assist in communication between the grower/processor and the dispensary.
§ 1151a.36. Transport manifest.	(d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products described in the transport manifest. To maintain confidentiality, a grower/processor may	Amend (d) to include that a grower/processor must send the transport manifest to the dispensary in an appropriate amount of time prior to delivery.

	prepare separate manifests for each recipient.	
1151a.40. Management and disposal of medical marijuana waste.	(e) Wastewater or spent hydroponic nutrient solution generated or produced from the growing, harvesting or processing of immature medical marijuana plants or medical marijuana plants shall be managed in accordance with one of the following: (1) Discharged into a permitted sewage treatment system in accordance with local, Federal and State requirements, including The Clean Streams Law (35 P.S. §§ 691.1—691.1001) and 25 Pa. Code Chapter 92a (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance). (2) Treated and discharged into waters of the Commonwealth under a National Pollutant Discharge Elimination System permit or water quality management permit in accordance with the requirements of The Clean Streams Law, including 25 Pa. Code Chapter 91 (relating to general provisions) and 25 Pa. Code Chapter 92a. (3) Disposed in a municipal waste landfill if placed in a container that is less than one gallon in size.	Amend (3) include language that allows for disposal of medical marijuana waste at the dispensary. Similar to retail pharmacy disposal of controlled substances, a witness or third party may be required for the destruction or disposal of medical marijuana products at the dispensary.
§ 1151a.42. Complaints about or recall of medical marijuana products	(a) A dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following requirements apply: (1) A grower/processor shall immediately investigate a complaint to determine if a voluntary or mandatory recall of seeds, immature medical marijuana plants, medical marijuana	Amend (a) to modify language to indicate that a dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question within a **reasonable amount of time** upon becoming aware of any **adverse event** by having the medical professional on duty at the dispensary complete the Department's Adverse Event Form. Reason: Patient complaints differ from adverse events. Patients may complain about taste, smell, reviews they see online, etc., which would not warrant investigation of an adverse event. The medical

	plants, medical marijuana or medical marijuana products is necessary or if any further action is required. (2) If a grower/processor determines that further action is not required, the grower/processor shall notify the Department of its decision and, within 24 hours, submit a written report to the Department stating its rationale for not taking further action.	professional on duty at the dispensary should be the only employee eligible to complete the Department's Adverse Event Form, as they have received prior education regarding reporting adverse events and are able to appropriately differentiate between a complaint and an adverse event.

§ 1151a.42. Complaints about or recall of medical marijuana products.	(a) A dispensary may only dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee at the facility who is authorized to dispense medical marijuana products at the facility. (b) Prior to dispensing medical marijuana products to a patient or caregiver, the dispensary shall: (1) Verify the validity of the patient or caregiver identification card using the electronic tracking system. (2) Review the information on the patient's most recent certification by using the electronic tracking system to access the Department's database. The following requirements apply: (i) If a practitioner sets forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical marijuana product dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements or limitations. (ii) If a practitioner does not set forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the physician, pharmacist, physician assistant or certified registered nurse practitioner employed by the dispensary and working at the facility shall consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed. (iii) The dispensary shall update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical marijuana product that is dispensed to the patient.	Amend (b)(2) to indicate that the medical professional on staff reviews the information on the patient's most recent certification. This task cannot be delegated to anyone other than another medical professional employed by the dispensary. Amend language in (b)(2)(ii) to indicate that the patient has the option to deny consultation with the dispensary's medical professional if the certifying practitioner does not set forth recommendations, requirements, or limitations in the certification. The way it is written indicates that consultation would need to occur at every visitation and this is not necessary for every patient or a viable option for the current medical professional to employee ratio at dispensaries. This would also prohibit providing online ordering as a service to patients. Amend (b)(2)(iii) to state that the medical professional on staff at the dispensary will update the patient certification in the electronic tracking system by entering the recommendation, **if any**, that was made on the date of purchase.

	This proposed section mirrors the current § 1151.42 (relating to complaints about or recall of medical marijuana products), with two exceptions, as detailed as follows. This proposed section provides that in the event of a complaint of an adverse event from using medical marijuana, a dispensary must notify the Department and the grower/processor from which it purchased the medical marijuana and outlines the grower/processor's subsequent investigatory and reporting obligations. Further, this proposed section addresses processes and procedures in the event of a voluntary or mandatory recall of medical marijuana or medical marijuana products, subject to penalties for noncompliance; specifies the information that must be entered into the electronic tracking system; and specifies the requirements of a recall plan.	Additional Comment: Does this mean <u>every</u> adverse event or do we want to specify or define a serious adverse event for this section? We advise patients on dosing and to decrease doses when side effects are occurring and the determination that there may be a product problem in these examples is rarely a concern.
§ 1161a.23. Dispensing medical marijuana products.	(c) Prior to the completion of the transaction, the employee conducting the transaction at the dispensary shall prepare a receipt of the transaction, and file the receipt information with the Department utilizing the electronic tracking system. A dispensary shall provide a copy of the receipt to the patient or the caregiver, unless the patient or the caregiver declines the receipt. The receipt must include all of the following information: (1) The name, address and any permit number assigned to the dispensary by the Department. (2) The name and address of the patient and, if applicable, the patient's caregiver. (3) The date the medical marijuana product was dispensed. (4) Any requirement or limitation noted by the practitioner on the patient's certification as to the form of	Remove (4) as a requirement for receipt information. Reason: Often this information is not included or it is written in medical jargon or abbreviations that are not common for the layman. Another reason to omit this information is because it is an identifying data point that further establishes the receipt as a form of protected health information.

	medical marijuana product that the patient should use. (5) The form and the quantity of medical marijuana product dispensed. (d) Except as provided in sections 2001—2003 of the act (35 P.S. §§ 10231.2001—10231.2003) and this part, a dispensary shall destroy any paper copy of the patient certification or delete any electronically recorded patient certification stored on the dispensary's network, server or computer system as the result of a transaction after the receipt relating to that transaction has been filed under subsection (c). This proposed section mirrors the current § 1161.23 (relating to dispensing medical marijuana products). This proposed section provides that a dispensary may only dispense to individuals who present a valid identification card; specifies the necessary prerequisites the dispensary must complete before dispensing medical marijuana products and before completing a transaction, including information that must be listed on a receipt and recordkeeping requirements.	Comment: There is some confusion around what is meant by a "valid identification card." Many dispensaries require you to show a PA or other government-issued ID as well as the PA Patient or Caregiver ID card before entering the dispensary and others may only ask for the PA Patient card. Please clarify which identification cards are required, if more than just the Medical Marijuana ID card is required.
§ 1161a.24. Limitations on dispensing.	(a) A dispensary may not dispense to a patient or caregiver: (1) A quantity of medical marijuana product that is greater than the amount indicated on the patient's certification. (2) A form or dosage of medical marijuana that is listed as a restriction or limitation on the patient's certification. (3) A form of medical marijuana product not permitted by the Act or this part, unless otherwise provided in regulations adopted by the Department under section	Remove (a)(1) because quantities are not indicated on certifications by certifying physicians unless it is a restriction or limitation. Remove (b) entirely. Day supply is irrelevant because it may differ greatly from patient to patient based upon patient experience and tolerance. Instead, consider including language that indicates that quantity limitations are enforced by the discretion of the medical professional on staff at the dispensary.

	1202 of the Act (*35 P.S. § 10231.1202)* (b) A dispensary may not dispense an amount of medical marijuana product greater than a 30-day supply to a patient or caregiver until the patient has exhausted all but a 7-day supply provided under the patient certification currently on file with the Department. This proposed section mirrors the current § 1161.24 (relating to limitations on dispensing). This proposed section provides that a dispensary may only dispense medical marijuana or medical marijuana in a quantity or form provided for on the patient's certification and permitted by the act or these proposed regulations. This proposed section also prohibits a dispensary from dispensing more than a 30-day supply of medical marijuana to a patient and not before the patient has exhausted all but a 7-day supply of medical marijuana.	Comment: does this mean based on whether the certifying doctor lists any restricted forms or based on the certifying condition? It is challenging to interpret the check boxes next to some forms since those are not in alignment with the names of the forms on the dispensary menus. Comment: It is not possible to estimate whether a patients have less than a 7-day supply left of medicine at home because a one-day supply varies from patient to patient. Similar to prescription medications, there are forms of cannabis that may be used for maintenance of chronic conditions and daily or more than once daily. We also have some "as needed" cannabis medications that may last longer depending on how often they are used per month.
§ 1161a.25. Licensed medical professionals at facility.	(a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is present at the facility at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers.	Amend (a) to allow for remote certification and remote counseling during pre-coordinated times with the Department. Amend (c) to indicate that completion of the training is required every **two** years and the Department

	(b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be present onsite at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always present at one of the facilities. (c) As required under the act, a physician, a pharmacist, a physician assistant or a certified registered nurse practitioner shall, prior to assuming any duties at a facility, successfully complete a 4-hour training course developed by the Department. The course must provide instruction in the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the Department. (d) Successful completion of the course required under subsection (c) shall be approved as continuing education credits as determined by: (1) The State Board of Medicine and the State Board of Osteopathic Medicine. (2) The State Board of Pharmacy. (3) The State Board of Nursing. (e) A practitioner or a physician, while at the facility, may not issue a patient certification to a patient. This proposed section mirrors the current § 1161.25 (relating to licensed medical professionals at facility), with one addition, as detailed as follows. This proposed section provides that a physician or pharmacist must be present at the facility during operating hours and, if a permittee operates more than one facility under the same permit, a physician assistant or certified nurse practitioner may cover the other sites.	will update the training every year to include any amendments, announcements, etc. that are pertinent to the medical professionals who operate within the PAMMJ program. Comment: see also 1181a.32. The Department will provide a list of approved training providers for the Continuing Education programs required for medical professionals.

	Further, this proposed section provides training requirements and continuing education standards for physicians, pharmacists, physician assistants and certified nurse practitioners. This section also prohibits a practitioner or physician from issuing patient certifications while at the facility.	
§ 1161a.32. Inventory data.	(a) A dispensary shall maintain the following inventory data in its electronic tracking system: (1) Medical marijuana products received from a grower/processor (2) Medical marijuana products dispensed to a patient or caregiver (3) Damaged, defective, expired, or contaminated medical marijuana products awaiting return to a grower/processor or awaiting disposal (b) A dispensary shall establish inventory control and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical marijuana products at its facility (c) A written or electronic record shall be created and maintained of each inventory which includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.	Amend (1) that accuracy of package ID and batch number are required to ensure appropriate documentation from seed to sale. Failure to secure accurate package ID and batch number may lead to **adulteration** or **misbranding** of medical marijuana products. Misbranding: https://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding Added Note: The label must have adequate directions for use or include appropriate warnings required to protect those using the medication or packaging. See the following examples below (these are not inclusive of all considerations): *Cartridges*: Intended to be used with an appropriate battery as identified by the grower/processor based upon cartridge hardware. Ex. Use with a 510-thread battery; Not intended for use with draw activated batteries; *Topical products*: Apply (*insert amount*) liberally/sparingly to the affected area. Warn if it should not be used on broken skin or a mucous membranes, etc. *Capsules*: Intended for oral consumption;

		Tablets: Can/cannot be broken or crushed; *Tinctures/Oral Solutions*: For sublingual/oral use; *Concentrates*: Intended for use in an approved vaporization device *Dry Flower Preparations*: It is illegal to combust flower in Pennsylvania Adulteration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=225.1
§ 1161a.36. Transport manifest.	(a) A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information: (1) The name, address and permit number of the dispensary, and the name of and contact information for a representative of the dispensary who has direct knowledge of the transport. (2) The name, address and permit number of the medical marijuana organization receiving the delivery, and the name of and contact information for a representative of the medical marijuana organization. (3) The quantity, by weight or unit, of each medical marijuana harvest batch, harvest lot or process lot contained in the transport, along with the identification number for each harvest batch, harvest lot or process lot. (4) The date and approximate time of departure. (5) The date and approximate time of arrival. (6) The transport vehicle's make and model and license plate number.	Amend (7)(c) to include verbiage allowing items to be returned without proper labeling if they were purchased prior to recording all inventory transactions in MJ Freeway. Reason: MJ Freeway was not ready for use until approximately 06/2018, therefore dispensaries who operated from 02/2018-06/2018 are unable to return items that were purchased and dispensed during this time period.

	(7) The identification number of each member of the delivery team accompanying the transport. (b) When a delivery team delivers medical marijuana products to multiple facilities, the transport manifest must correctly reflect the specific medical marijuana products in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana products received. (c) All medical marijuana products being transported shall be labeled in accordance with §§ 1151a.34 and 1161a.28 (relating to packaging and labeling of medical marijuana products; and labels and safety inserts) and shall be transported in a secure lockbox located within a locking cargo area. (d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana products described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient. (e) A dispensary shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.	
§ 1161a.38. Complaints about or recall of medical marijuana products.	(a) A dispensary shall notify the Department and the grower/processor from which it received the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products dispensed by the dispensary.	Amend the language in (a) to indicate the dispensary shall notify the Department and the grower/processor from which it received the medical marijuana product in question **as soon as reasonably possible** upon becoming aware of an adverse event. Amend the language in (a) to also acknowledge there is a difference

	(b) Upon notification by the grower/processor under § 1151a.42 (relating to complaints about or recall of medical marijuana products), the dispensary shall cease dispensing the affected medical marijuana products immediately. (c) A dispensary shall coordinate the return of the recalled medical marijuana products with the grower/processor.	between a complaint and an adverse event; not all complaints are adverse events. Question: Is the reason for this regulation to discover a product problem? NCCMERP categories for medication error events in the prescription drug realm. https://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf https://www.nccmerp.org/
§ 1181a.23. Medical professionals generally.	(a) The qualifications that a medical professional shall meet to be employed by a dispensary are continuing qualifications. (b) A medical professional may not assume any duties at a dispensary until the training required under § 1181a.32 (relating to training) and any other requirements for medical professionals under the act and this part are completed. (c) A medical professional shall notify by telephone the practitioner listed on a patient certification of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction. This proposed section mirrors the current § 1181.23 (relating to medical professionals generally), except for revising a citation in subsection (b) to refer to this proposed chapter. This proposed section provides that, like the requirements for a registered practitioner, the requirements to be a registered medical professional are an ongoing responsibility to maintain. The proposed section also provides that a medical professional may not assume any duties at a dispensary until all requirements are satisfied.	Amend (c) to allow for email communication based upon the email address provided by the certifying physician to the DOH. It is not always possible to reach the certifying physicians via telephone and the language here does not indicate that it is acceptable to leave a voicemail or message with an agent of the certifying physician. Additional Comment: Is it required to report "any adverse reaction" vs a serious adverse reaction? Cannabis is generally very safe and has a wide safety profile resulting in a wide range of safe and effective doses that do not cause adverse reactions. The most common Adverse Events that have been reported have been considered expected side effects of cannabis, especially when it is taken in larger

	This proposed section further requires that a medical professional notify the practitioner listed on the patient certification of any adverse reaction suffered by the patient as a result of interaction with a medical marijuana product purchased at the dispensary.	amounts than the individual can tolerate. These include nausea, vomiting, headache, dizziness, drowsiness, increased heart rate, anxiety, and increased anxiety leading to paranoia. Comment: The practitioner that certifies the patient is not commonly involved in the other aspects of the medical management of that patient. Medical Professionals, in this proposed regulation, are required to notify the certifying doctor of any adverse reactions. It may be more appropriate to assist the patient as needed (and with the patient's permission) in communicating details of the regimen to their actual primary care physician or specialist involved in the management of their medical conditions.
§ 1181a.27. Issuing patient certifications.	(a) A practitioner may issue a patient certification to a patient if the following conditions are met: (1) The practitioner has determined, based upon a patient consultation and any other factor deemed relevant by the practitioner, that the patient has a serious medical condition and has included that condition in the patient's health care record. (2) The practitioner has determined the patient is likely to receive therapeutic or palliative medical benefit from the use of medical marijuana based upon the practitioner's professional opinion and review of the following: (i) The patient's prior medical history as documented in the patient's health care records if the records are available for review.	Amend (a)(2)(i) to remove "if the records are available for review." The records must be kept and maintained by the physician as proof of patient-physician interaction and validity of serious or chronic medical condition. Amend (2)(ii) to indicate that the certifying physician must check the patient's controlled substance history through the Prescription Drug Monitoring Program website. Reason: The information is accessible to all prescribers and pharmacists who practice in Pennsylvania. Amend (c)(11) to include a statement by the practitioner indicating that the patient is not pregnant or breastfeeding, if applicable. If the patient does become pregnant or

	(ii) The patient's controlled substance history if the records are available in the Prescription Drug Monitoring Program. (b) Notwithstanding subsection (a), the following requirements apply: (1) A practitioner who is not board-eligible or board-certified in pediatrics or a pediatric specialty, neurology with special qualifications in child neurology, child and adolescent psychiatry, or adolescent medicine (whether through pediatrics, internal medicine or family practice) may not issue a patient certification to a minor patient. (2) Paragraph (1) will be effective upon the registration of a sufficient number of eligible practitioners to ensure adequate access for minor patients needing services under the act and this part based on location, serious medical condition and number of patients, specialty, and number and availability of practitioners. The Department will publish a notice in the *Pennsylvania Bulletin* 1 month before paragraph (1) becomes effective, stating that a sufficient number of eligible practitioners have registered to effectuate this subsection. (c) A patient certification that is issued by a practitioner must include, at a minimum, all of the following: (1) The patient's name, home address, telephone number, date of birth and e-mail address, if available. (2) The practitioner's name, business address, telephone numbers, professional email address, medical license number, area of specialty, if any, and signature. (3) The date of the patient consultation for which the patient certification is being issued. (4) The patient's specific serious medical condition. (5) A statement by the practitioner that the patient has a serious medical	begins breastfeeding, it is the patient's responsibility to notify their certifying practitioner so that they can assess whether cannabis use is appropriate at this time. (c)(13) A statement by the practitioner that current prescription medications have been reviewed. Amend (d)(1) include: The certifying physician will review any limitations or restrictions on the certification with the patient or caregiver.

	condition, and the patient is under the practitioner's continuing care for the condition. (6) A statement as to the length of time, not to exceed 1 year, for which the practitioner believes the use of medical marijuana by the patient would be therapeutic or palliative. (7) A statement by the practitioner that includes one of the following: (i) The recommendations, requirements or limitations as to the form or dosage of medical marijuana product. (ii) The recommendation that only a medical professional employed by the dispensary and working at the dispensary facility consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed. (8) A statement by the practitioner that the patient is terminally ill, if applicable. (9) Any other information that the practitioner believes may be relevant to the patient's use of medical marijuana products. (10) A statement that the patient is homebound or an inpatient during the time for which the patient certification is issued due to the patient's medical and physical condition and is unable to visit a dispensary to obtain medical marijuana products. (11) A statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana products to the patient and has documented in the patient's health care record that the explanation has been provided to the patient and informed consent has been obtained. (12) A statement that a false statement made by the practitioner in the patient certification is punishable under the applicable provisions of 18	

	Pa.C.S. Chapter 49 (relating to falsification and intimidation). (d) Upon completion of a patient certification, a practitioner shall: (1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient. (2) Provide the patient certification with the original signature to the Department, which may be submitted electronically. (3) File a copy of the patient certification in the patient's health care record.	

§ 1181a.28. Modifying a patient certification.	(a) A practitioner may not modify the form of medical marijuana products on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system by the dispensary unless the practitioner notifies the Department of the intent to modify the patient certification. (b) After modifying a patient certification, a practitioner shall do the following: (1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient. (2) Provide the patient certification with the original signature to the Department, which may be submitted electronically. (3) File a copy of the patient certification in the patient's health care record. This proposed section mirrors the current § 1181.28 (relating to modifying a patient certification). This proposed section provides that a practitioner may not modify the form of medical marijuana products specified on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system unless the practitioner notifies the Department. This proposed section also requires a practitioner to provide a copy of a modified patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file.	Amend (b)(2) to include: at which point the Department will generate an update or obvious statement on the patient's certification in Oracle. Comment: Clarification is needed. There is no need for copies to be provided since it is available on the website unless patients do not have access to a computer to print. This applies to 1181a.27 as well. Comment: We saw an uptick in practitioner's listing "no inhaled forms" when the pandemic started and that was by mistake. In order to modify this as "not a firm restriction" for that individual patient and more of a general recommendation, the practitioner would have to wait 30 days to make any changes to the certification. Question: Why is there a 30-day waiting period for the practitioner? Question: Do practitioners know to

		contact the Department to change certifications?
§ 1181a.32. Training.	(a) Within the time specified, the following individuals shall complete a 4-hour training course approved by the Department. This proposed section mirrors the current § 1181.32 (relating to training), except for revising a citation in subsection (a) to refer to this proposed chapter. This proposed section specifies those individuals who must complete a 4-hour training course prescribed by the Department and the requirements of that training course. Further, this proposed section provides that completion of the training course	Amend (a) to indicate that the 4-hour training will be required every **two** years by participating medical professionals. Question: What is the approval process for Continuing Education training by the Department? Who reviews the content?

	qualifies as continuing education credits by certain medical boards, and that individuals who completed the training course must submit documentation to that effect to the Department. Finally, this proposed section provides that the Department will provide on its website a list of approved training providers.	
§ 1191a.26. Application fees.	(a) An applicant shall pay no more than one fee of $50 in a 12-month period for an identification card with an identification card application.	Amend (a) to indicate that the date of application fees will be stated on the patient's certification in Oracle. Reason: When patient or caregiver's cards are rejected in MJ Freeway, the dispensary is unable to discern the reason why if the expiration date on the card is valid. The "created date" of the card, the date of patient consultation, and the treatment period for the certification are able to give the dispensary clues to why the card is rejected, but they often do not correspond to the date of application fees.
1161a.28 Labels and Safety Inserts	This proposed section mirrors the current § 1161.28 (relating to labels and safety inserts), with two exceptions, as detailed as follows. This proposed section sets forth the requirements of what must, and what may not, be listed on a label, in subsections (c) and (d), respectively, in addition to requiring, in subsection (b), that any product sold to a patient be fully sealed and labeled. Further, proposed subsection (c) requires a dispensary to inspect labels to ensure that the label contains all required information and is firmly affixed to the container holding medical marijuana, and proposed subsection (e) prescribes standards for safety inserts.	Amend (c) to add that containers holding medical marijuana will not be subject to this requirement if the container is housed inside a sealed, outer package.

§ 1141a.46. Reports	This proposed section largely mirrors the current § 1141.46 (relating to reports), except for proposed revisions to subsection (a), as detailed as follows. *Subsection (a).* This proposed subsection outlines the ongoing reports medical marijuana organizations must provide to the Department and details the required contents of the reports. Proposed revisions to subsection (a)(1) and (2) require dispensaries and growers/processors to report the ''average price per unit of medical marijuana products sold'' rather than the ''per-dose price.'' These revisions are necessary because a ''dose'' varies from one patient to another and from one product to another.	Comment: There is uniformity with the unit sizes in some forms of cannabis in our program (i.e. flower is 1 g, 3.5 g or 7g, and cartridges are 500 mg or 1 gram etc.). However, the tinctures and solutions vary in mL per bottle. We have 12.5 mL, 15 mL and 30 mL bottles so far. The ingested forms may vary in number of capsules or tablets or softgels per bottle.
§ 1171a.36. Advertising.	This proposed section mirrors the current § 1171.36 (relating to advertising). This proposed section prohibits a laboratory from advertising or promoting its services to the general public. This proposed section clarifies that personal solicitation by a laboratory employee is considered advertising or promotional marketing. It also provides that a laboratory may only advertise to a grower/processor those services performed on site, subject to prior Department approval. Further, this proposed section provides that a laboratory may erect signage at its facility, subject to compliance with local zoning requirements and this proposed section.	Question: Does this mean only the grower/processor may call the lab? If a lab employee calls the grower/processor, it is considered advertising. Consider clarification of this section.

§ 1181a.24. Physician registration		Question: Is the certifying physician required to be based in PA? Comment: As pharmacists operating in dispensaries, we have noticed some addresses outside of PA and with non-PA zip codes when we verify certifications.
§ 1181a.31. Practitioner prohibitions	This proposed section mirrors the current § 1181.31 (relating to practitioner prohibitions), except for adding subsection (g). This proposed section lists the prohibitions for practitioners, including: (1) accepting any form of remuneration for issuing patient certifications other than a fee for the patient consultation; (2) holding a direct or economic interest in a medical marijuana organization; (3) advertising as a certifying physician; (4) issuing a patient certification for personal use or for a family or household member; (5) acting as a caregiver for a patient certified by the practitioner; and (6) receiving or providing medical marijuana samples. In addition, proposed subsection (g) prohibits a practitioner from charging patients excessive fees. The Department is proposing the change due to patient complaints of practitioners taking advantage of the certification process by charging excessive lab testing, follow-up, or other fees not initially disclosed. Section 301(a)(11) of the act (35 P.S. § 10231.301(a)(11)) provides that the Department ''shall collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act.'' The Department will collaborate with the Department of State	Comment: The variance in cost of certifications is a problem we have noticed. One psychiatrist has been charging patients almost $400 for a three-month certification and requiring follow up visits. In this case, the doctor is setting the patient up for four certifications and fees annually instead of authorizing a 12-month certification with one fee annually. Although we cannot dictate how they practice, it is a common and forefront complaint that the Program is too expensive. Consider implanting caps on certifications dependent upon recertification period. In some cases, a primary care physician may certify a patient who also sees them for another purpose such as an annual physical. These physicians waive the fee completely. Most commonly, we see certifications for one year and no restrictions; the doctor is not the patient's PCP or specialist for any other reason than the certification. Comment: There is another practice that authorizes less than one-year certifications and it appears that the patients may or may not be in the practice for other purposes (PCP).

	(DOS), which licenses physicians, and refer for investigation complaints that a practitioner is engaging in unscrupulous billing practices. The DOS will investigate and, if the DOS finds a violation of the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.51a), or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18), the DOS will impose sanctions. If the DOS suspends, revokes, limits or otherwise restricts the practitioner's license, the practitioner will be removed from the medical marijuana physician registry under proposed § 1181a.26(a).	
§ 1191a.28. Identification cards	This proposed section mirrors the current § 1191.28 (relating to identification cards), with one exception, as detailed as follows. This proposed section provides that the Department will issue identification cards as soon as practicable, and requires that the card contain certain delineated information, including a photograph of the cardholder. Subsection (c) provides that the Department will not require a photograph if the applicant submits a statement that a photograph cannot be provided due to the applicant's religious beliefs. Further, this proposed section outlines the circumstances under which an identification card issued to a patient or caregiver will expire. This proposed section omits the requirement in current subsection (f) that cardholders apply for a replacement card within 10 business days of discovering the loss or defacement of the card, as this requirement has been moved to proposed § 1191a.24(b) (relating to cardholder responsibilities).	Question: Is this equal to how we handle PA issued IDs or passports?
§ 1191a.31. Obtaining medical marijuana products	This proposed section mirrors the current § 1191.31 (relating to obtaining medical marijuana products from a	Comment: Usually there are no restrictions. It is preferred to leave the selection of appropriate forms

from a dispensary	dispensary), except for amending citations have been amended throughout this section to refer to proposed Chapters 1161a and 1181a (relating to practitioners; and dispensaries). This proposed section provides that a medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with proposed § 1161a.24 (relating to limitations on dispensing), and that the cardholder may only obtain medical marijuana products from a dispensary based on the recommendation provided in a valid patient certification that the dispensary may access through the electronic tracking system.	to the medical professionals that are actually working inside the dispensary to avoid recommendations that make no sense such as recommendations for products that do not exist in our PA program.

§ 1161a.27. ***Items and services provided at a dispensary***	*Subsection (d).* Aside from revising one citation to refer to proposed Chapter 1151a (relating to growers/processors), this proposed subsection mirrors the current subsection (d). This proposed subsection provides that dispensaries may dispense a medical marijuana product with a THC concentration of less than 0.3% if purchased from a grower/processor that has obtained prior Department approval. *Subsection (e).* This proposed subsection delineates prohibited actions for a dispensary. Specifically, dispensaries may not (1) provide medical marijuana product at no cost unless the patient is approved for financial assistance by the Department; (2) make purchases conditional upon the patient purchasing a medical device at the facility or a separate facility; (3) deliver, or contract with a third party to deliver medical marijuana; and (4) sell items and services unrelated to the use of medical marijuana products. This proposed subsection removes the current prohibition on advertising activities, as that provision caused confusion. The removal of this subsection does not, however, negate the general requirement in proposed § 1141a.50(b) (relating to advertising by a medical marijuana organization) that all promotional, advertising and marketing materials must be approved by the Department prior to use. Further, this proposed subsection revises the prohibition on delivering medical marijuana products by prohibiting a dispensary from contracting delivery to third parties, in addition to prohibiting a dispensary from delivering to a patient or caregiver, and by adding a prohibition on the sale of items unrelated to the	(d) Question: Does this mean that dispensaries in PA can sell hemp-based CBD products inside the dispensary? Can the growers of the hemp-based CBD products be based or located outside of PA? (d) Question: Is the intent of this proposed regulation meaning for the grower/processors of medical cannabis in PA to also offer hemp-based CBD products in PA that may be sold in the dispensary? (e) Comment: Does this mean that dispensary employees are not allowed to become caregivers for patients? Does this mean that caregiver volunteers are not permitted? (e.g. Soulful Cannabis). Soulful Cannabis connects volunteers directly with patients that may still be waiting for a family member to get their caregiver card.

	use of medical marijuana. These revisions seek to limit the services a dispensary may provide to a patient or caregiver that are unrelated to the sale of medical marijuana products.	
§ 1161a.28. Labels and safety inserts	Compared to the requirements in current § 1161.28, this proposed section adds the requirements that all cannabinoids and terpenes and corresponding percentages be listed on the label and that a label be firmly affixed to a container directly holding medical marijuana.	Comment: It may be challenging to list ALL the terpenes on the container labels. There are 100s of terpenes within the cannabis plant. Consider revising to require growers to list the **top five** terpenes or other agreed upon number of terpenes on the container labels. In pharmaceuticals, the container is the part of the package that is in direct contact with the medicine. The carton is the packaging that houses a container; safest is for the container to be adequately labeled. Comment: At this time we have multiple growers with multiple forms listing this on the carton but not the containers. By doing this, the result is that patients may have unlabeled containers of cannabis medicines at home. This may make it difficult to administer and adjust the dosing of the medicines as needed. What about Package Inserts attached to the container? Comment: For some ingested forms, we prefer to have the milligrams of the cannabinoids per mL (or per capsule) and per container.

§ 1161a.30. Access to dispensary facilities	*Subsection (f).* Proposed subsection (f) mirrors the current subsection (f). This proposed subsection provides that nothing in proposed § 1161a.30 will limit the right of the Department or its authorized agents, or State or local law enforcement or other Federal, State or local government officials from entering any area of a grower/processor site or facility, if entrance is necessary to perform their functions and duties that pertain to the act or this proposed part.	Question: Are firefighters included in this?
§ 1171a.25. Renewal of an approval issued to a laboratory	This proposed section mirrors the current § 1171.25 (relating to renewal of an approval issued to a laboratory), except for revising a citation to refer to this proposed chapter. This proposed section provides the timeframe in which an approved laboratory must submit an application for renewal.	Questions: How frequently do the labs need to submit for renewal? How many labs will a grower/processor typically use on a regular basis?
§ 1171a.29. Testing requirements	*Subsection (g).* This proposed subsection (g) specifies tracking and disposal requirements. Where the current subsection (g) requires that all tests be entered into the electronic tracking system, this proposed subsection (g) provides that only testing performed on samples of harvest lots and process lots must be entered into the electronic tracking system, which and allows for additional tests to be performed without being entered into the electronic tracking system. Many permittees have requested the ability to conduct additional testing prior to harvesting. Additionally, a citation has been amended to refer to this proposed	Comments: "and" may be a typo; should be "or". **28 Pa. Code § 1151.34.** (7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each **harvest lot or process lot** in the harvest batch. Comments: Why are grower/processors requesting additional testing prior to harvesting? And why don't those additional tests have to be entered into the electronic tracking system?

	chapter and the proposed Chapter 1151a.	
§ 1171a.35. Laboratory reporting	*Subsection (b).* This proposed subsection provides that an approved laboratory maintain a certificate of analysis for 4 years and amends the current subsection to include those test results not required to be entered into the electronic tracking system. Additionally, proposed amendments to this subsection add paragraph (1), which requires an approved laboratory to immediately provide to the Department an electronic copy of a certificate of analysis for those test results that are not required to be entered into the electronic tracking system, and paragraph (2), which modifies the current subsection (b) to apply only to results entered into the electronic tracking system.	Comments: Consider clarification.
Add'l comments	35 P.S. 10231.1105 Official Report 5/20 1. Medical Conditions 2. Physician Workgroup - Section 1105(b)(2), pg 10 3. Diverse Participants - Chapter 1141a, pg 5. General Provisions	1. Medical Conditions: Add Insomnia 2. Physician Workgroup: It would be great to have a dispensary Medical Professional be a part of this group. 3. Amend (ii) Omit *Women.* Reason: Women made up 50.8% of the US population in 2020; Webster's defines diversity as "any difference". It's time to recognize that women are equal to men.
General Recommendation	The Department has appointed patient/caregiver workgroups and physician workgroups. However, the Department has not defined a work group specific to the medical professionals who work in a dispensary.	It is necessary to establish this Medical Professional Work Group so there is harmony amongst all aspects of dispensing MMJ products. This workgroup should be established and acknowledged in the same respect as the other Department workgroups.

§ 1211a.29. Practices and procedures of research programs, projects or studies	This proposed section mirrors the current § 1211.29 (relating to practices and procedures of research programs, projects or studies). This proposed section requires medical marijuana to be dispensed to a patient or caregiver as part of a research program in a form that conforms to the act or this proposed part. This proposed section further provides that medical marijuana may be dispensed from a clinical registrant directly to an ACRC in any form deemed safe by an IRB. This proposed section further provides requirements for research approval committees and IRBs, including (1) establishing policies and procedures, (2) reviewing research studies and (3) ensuring each research study addresses the issues specified in proposed subsection (e).	Question: Are patients in the research programs still paying for the cannabis medicines or are the research projects funded in some other way? Question: Are we seeing research on new forms of cannabis or is the research more on specific responses for various symptoms or conditions?
§ 1211a.30. Approval or denial of an application for approval of a clinical registrant	This proposed section mirrors the current § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant), except for revising citations to refer to this and other proposed chapters. This proposed section provides that an applicant shall be an approved clinical registrant upon the Department's approval of an application under proposed § 1211a.27 (relating to application for approval of a clinical registrant). This proposed section further provides that the Department may deny the application if the applicant has disclosed prior payments to a certified ACRC. This proposed section also specifies that prior to denying an application, the Department will issue written notice to the applicant and the applicant will have the opportunity to cure the prohibited payments by submitting to	Comment: Need clarification on the context for this proposed regulation and the prohibited payment. Comment: Generally, we are unfamiliar with the timelines and status of cannabis research in PA.

	the Department a supplemental affidavit indicating that the certified ACRC or its affiliate has refunded to the applicant the prohibited payment. Further, this proposed section provides that an approved clinical registrant will have the same rights and obligations as a grower/processor or dispensary permittee, and a clinical registrant's dispensary and grower/processor permits will expire upon expiration, revocation or nonrenewal of the clinical registrant's approval.	
§ 1211a.33. Dispensing and tracking medical marijuana products	This proposed section mirrors the current § 1211.33 (relating to dispensing and tracking medical marijuana products), except for revising a citation to refer to proposed Chapter 1161a (relation to dispensaries). This proposed section provides that the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department identifying patients who are enrolled in an approved research program or research study, in addition to entering information about medical marijuana products dispensed to all patients and caregivers.	Question: Where will this be documented in MJ Freeway? Is this happening already?
§ 1211a.36. Sale or exchange	This proposed section mirrors the current § 1211.36 (relating to sale or exchange), except for revising a citation to refer to this proposed chapter. This proposed section outlines the items a grower/processor of a clinical registrant may sell or exchange with another grower/processor and provides that a grower/processor of a clinical registrant may only sell its medical marijuana products to its own dispensary or to a dispensary owned by another clinical	Comment: It seems there may be issues with research if the grower/processor is unable to provide a consistent product or access to a product on a consistent basis. We see this in the dispensary in general already. Patients are frustrated when their tincture that worked so well last time is no longer available and may never be created again. Question: Does the dispensary

	registrant. This proposed section further provides that an approved clinical registrant may petition the Department to sell its medical marijuana products to a dispensary in the commercial market and specifies that the petition must include the report required by proposed § 1211a.35 (relating to reporting requirements).	connected to the research program no longer have exclusive access to the products from the grower/processor participating in the research program?
§ 1230a.39. Timeliness of Notice of Appeal	This proposed section amends the current § 1230.39 (relating to timeliness of Notice of Appeal), as detailed as follows. This proposed section provides that the timeliness of a Notice of Appeal is measured from the mailing date of the written notice of the action, and an untimely filed Notice of Appeal may be deemed an admission or be dismissed with prejudice. This proposed section further provides that the Department may file an answer and new matter to a Notice of Appeal within 30 days of service of the Notice, but is not required to do so. This proposed section proposes two amendments. First, proposed subsection (a) provides that the timeliness of an appeal will be measured from the mailing date of the written notice of the action instead of the date the appellant receives the written notice, as specified in the current subsection (a). This proposed amendment removes ambiguity relating to timeliness of appeals and removes the possibility for differing time periods for appeal. Second, proposed subsection (b) provides that an untimely filed Notice of Appeal may be deemed an admission or may be dismissed by the Department, instead of the language in the current § 1230.39 that one's ''failure to file'' a timely Notice of Appeal results in the same. This proposed amendment is a technical	Question: Is there a timeline or is it unlimited now? Comment: There have been some issues with US MAIL and delays during the pandemic that may impact timed communications via US MAIL.

	clarification. This proposed section also provides that proposed subsection (a) supersedes 1 Pa. Code §§ 35.5—35.7, 35.20 and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions).	
§ 1230a.46. Entry of default judgment	This proposed section mirrors the current § 1230.46 (relating to entry of default judgment). This proposed section provides that the Department, on motion of the Office, may enter default judgment against the respondent for failure to file within the required time an answer to an Order to Show Cause, order or other petition, to which the respondent may answer and have an opportunity to be heard; default judgment may not be granted prior to the hearing and the filing of an answer. C. *Affected Persons* Medical patients and their caregivers, as well as grower/processors and dispensary permittees and approved labs, will be required to comply with the provisions in this proposed rulemaking. Additionally, those individuals or entities that have not yet been issued a permit to receive, dispense or prescribe medical marijuana as well as successful future applicants will be required to comply with the provisions contained in this proposed rulemaking.	Comment: There is no "prescribing" of medical cannabis since it is still federally illegal. Question: Is it different within the research context? Comment: The role of the practitioner is to certify a patient who has an approved medical condition; the role of the medical professional is to assist the patient with information to make good choices and safely optimize the regimens.

