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Jeff Youtz
Director

December 11, 2009

Senator Robert L. Geddes
President Pro Tem of the Senate
Room 331
Statehouse Mail

Representative Lawerence Denney
Speaker of the House of Representatives
Room 301
Statehouse Mail

Re: Report of the Health and Welfare Germane Joint Subcommittee

Dear Pro Tem Geddes and Speaker Denney:

The Health and Welfare Germane Joint Subcommittee met on December 8, 2009, pursuant to section 67-454, Idaho Code, to review Docket No. 27-0101-0904, Rules of the Idaho State Board of Pharmacy. This rulemaking was conducted to implement the Idaho Legend Drug Donation Act, sections 54-1760 through 54-1765, Idaho Code, which was enacted by the 2009 Idaho Legislature. Present at the meeting were: Representative Sharon Block, who served as Chairperson; Senator Joyce Broadsword (telephonic); Senator John McGee (telephonic), who substituted for Senator Patti Anne Lodge; Senator Les Bock, who substituted for Senator Nicole LeFavour; Representative Pete Nielsen; and Representative John Rusche (telephonic).

The Germane Joint Subcommittee received testimony from: Dennis Stevenson, Rules Coordinator, Department of Administration, regarding the rulemaking process; and Mark Johnston, Executive Director of the Board of Pharmacy, regarding the development and current status of Docket No. 27-0101-0904. The Germane Joint Subcommittee received public comment from Representative Sue Chew; former Representative Margaret Henbest; Allen Frisk (telephonic), representing Capital Pharmacy Associates; Steven Reames, Executive Director of the Garden City Community Clinic; Dawn Weiler, Medical Director of the Friendship Free Clinic; and Sandra Evans, Executive Director of the Idaho Board of Nursing.

Following discussion, Senator Broadsword moved that the Germane Joint Subcommittee not object to Docket No. 27-0101-0904, to encourage the Board of Pharmacy to continue working on this rulemaking docket, to encourage the Board of Pharmacy to reopen the public comment period on this rulemaking docket, and to request Pro Tem Geddes and Speaker Denney to allow flexibility in the rule review process during the 2010 Legislative Session so that this rulemaking docket may be reviewed by the Senate and House of Representatives Health and Welfare Committees as a pending rule following its anticipated publication in February 2010. The motion was seconded by Representative Rusche and, following a discussion, passed unanimously by voice vote.

Please accept this letter as the report of this Germane Joint Subcommittee to the 2010 regular session of the Idaho Legislature pursuant to section 67-454, Idaho Code. Copies of this report are also being sent to the Board of Pharmacy and to the members of the Senate and House of Representatives Health and Welfare Committees as required by section 67-454.

Respectfully submitted:

Representative Sharon Block, Co-chairperson
Health and Welfare Germane Joint Subcommittee

cc: Mark Johnston, Executive Director, Board of Pharmacy; Members of the Senate and House of Representatives Health and Welfare Committees

MINUTES
(Subject to approval by the Health and Welfare
Germane Joint Subcommittee Co-chair)

HEALTH AND WELFARE GERMANE JOINT SUBCOMMITTEE MEETING
Re: Docket No. 27-0101-0904
DECEMBER 8, 2009
LEN B. JORDAN BUILDING
BOISE, IDAHO

Health and Welfare Germane Joint Subcommittee members in attendance were: Co-chair Representative Sharon Block, Representative Pete Nielsen, Representative John Rusche (via telephone conference call), Senator John McGee (serving for Co-chair Senator Patti Anne Lodge via telephone conference call), Senator Joyce Broadsword (via telephone conference call), and Senator Les Bock (serving for Senator Nicole LeFavour). Co-chair Senator Lodge and Senator LeFavour were absent and excused. Staff present were Paige Alan Parker and Charmi Arregui.

Other attendees were: Representative Susan Chew, District 17; former Representative Margaret Henbest, Terry Reilly Health Services Board and Executive Director, Idaho Alliance of Leaders in Nursing (IALN); Mark Johnston, Glenn Luke and Erick Lawton, Board of Pharmacy; Brad Iverson-Long, Idaho Reporter.com; Jenifer Marcus, Deputy Attorney General; Denise Chuckovich, Idaho Primary Care Association; Paul Leary, Department of Health & Welfare; Pat Lazare, Idaho Nurse Association; Steven Reames, Garden City Community Clinic; Dawn Weiler, Friendship Clinic; Sandy Evans, Board of Nursing; Colby Cameron, Sullivan & Reberger; Benjamin Davenport, Risch Pisca, PLLC; John Watts, Idaho Primary Care Association; Dennis Stevenson and Ed Hawley, Department of Administration; Dr. McClusky, Mustard Tree Clinic, Twin Falls, Idaho (via telephone conference call); and Allen Frisk, Capital Pharmacy Association, Boise, Idaho (via telephone conference call).

The meeting was called to order by **Co-chair Representative Block** at 10:33 a.m. **Representative Block** began by saying that the issue before the Health and Welfare Germane Joint Subcommittee involves Docket No. 27-0101-0904, rules promulgated by the Board of Pharmacy regarding the donation of drugs to free and low cost clinics in Idaho. These clinics perform important medical services for low-income citizens, especially in the current economy. **Representative Block** said the charge of this subcommittee is to resolve details of the issue of donation of legend drugs in a collaborative manner.

Mr. Dennis Stevenson, Rules Administrator, Department of Administration, informed the subcommittee with regard to the rules process. Board of Pharmacy Rule Docket #27-0101-0904 was published as a proposed rule in the October Administrative Rules Bulletin; the deadline date for submission of comments was October 28, 2009. One of the issues is that comments have been received after that deadline date, creating a legal issue if someone challenged this rulemaking based on that fact.

Mr. Stevenson recommended it would be prudent for the Board of Pharmacy to submit a Notice of Extension of Comment Period to allow comments received after the deadline to be included as part of this rulemaking. This would allow for additional comments to be submitted up and until the rule is submitted for publication in the bulletin as a pending rule and, if timely done, permit consideration of the docket by the Legislature as a pending rule in the 2010 session. If the Notice was published in the January 6, 2010 bulletin, the Board could receive additional comments with time to publish the docket as a pending rule in the February bulletin. The Speaker and the Pro Tem would have to make an exception to the end of January goal for the completion of the rules review in order to permit the Senate and House Health and Welfare Committees to review this docket after the February publication. According to **Mr. Stevenson,** that would be the cleanest, easiest way to get this issue resolved during this 2010 legislative session.

Senator Broadsword asked if this rule is rejected and the Board of Pharmacy came back with a temporary rule, would the temporary rule be heard during the 2010 legislative session. **Mr. Stevenson** answered that he didn't like the idea of simply rejecting the rule, coming back with a temporary rule, and having the same text being considered again. If the Board adopted a temporary rule after the 2010 legislative session, the temporary rule would not be required to be submitted for review and extension during that session. Only temporary rules adopted prior to the beginning of session are actually subject to review and extension. That doesn't preclude the legislative committees from requesting that such a rule be reviewed, since the Legislature has the authority to review any rules currently codified, including temporary rules.

Representative Rusche said that without a rule, there is basically no way for free clinics to accept donated medications. **Mr. Stevenson** confirmed that to be correct.

Senator McGee asked **Mr. Stevenson** for his procedural recommendation to make sure that review of this rule happens this year. **Mr. Stevenson** recommended that the Board publish a Notice of Extension to Comment Period, allowing comments received up this point in time to be included in changes made to the proposed rule. The Board could also schedule a public hearing to receive additional comments, if the Board deemed that to be necessary. Extending the comment period would require that the chairs of the Senate and House Health & Welfare Committees review this rule after its publication in the February bulletin and after the standard rule review period.

Senator Broadsword inquired how the extension of the comment period for this one rule would impact review of the rule in February. **Mr. Stevenson** responded that the omnibus concurrent resolutions only affect pending rules with fees or temporary rules that have been extended. If the present rule was presented to the Legislature as a pending rule, it would not be subject to an omnibus concurrent resolution and would go into effect unless specifically rejected, in whole or in part, by a separate concurrent resolution.

Representative Nielsen asked if it would be necessary for this subcommittee to adopt a motion to direct the Board to submit a Notice of Extension of Comment Period. **Mr. Stevenson** answered

that legally, the only action that the subcommittee is authorized to take is to adopt an objection to the rulemaking and to submit a report to the Senate and House germane committees regardless of whether an objection is adopted. This subcommittee does not have the power to suggest, require or force the Board into action. As a practical matter, **Mr. Stevenson** said that the Board will do what is suggested as a result of this meeting. He added that this meeting has become more like a public hearing than an actual legislative review of a proposed rule.

Representative Block invited **Mr. Mark Johnston**, Executive Director, Board of Pharmacy, to address Docket No. 27-0101-0904. **Representative Block** stated that she understood the importance of safeguarding the health of the public and expressed appreciation for the Board's cooperative manner in working through the public comment period. She expressed hope that the parties on both sides of the issue will cooperate in finding solutions to providing services to those in need in a safe manner.

Mr. Johnston said he was here to explain the creation of the proposed rule that was mandated by sections 54-1760 through 54-1765, Idaho Code. The Board did not take the requirement of promulgating this rule lightly, spending over 400 hours on this rulemaking. The Board consulted with the Attorney General's office and identified several issues:

(1) Nursing homes are listed as a donating entity but nursing homes don't own medications, thus a legal, personal property issue exists.
(2) Donating entities such as manufacturers have been legally donating drugs in the manufacturer's original sealed tamper-evident packaging, prior to the new legislation, which allowed, for the first time, nursing homes to donate previously dispensed drugs. This created the need for a more complex set of rules than first realized.
(3) The free clinics are not registrants with the Board and are not subject to inspection by the Board.

The Board's intent was to not complicate what was already legal, but the rulemaking had to be written to cover all the identified issues.

Mr. Johnston quoted section 54-1762(3)(a), Idaho Code:

> *Only drugs in the original sealed and tamper-evident packaging shall be accepted and dispensed except that drugs packaged in single unit doses may be accepted and distributed when the outside packaging is open and a single use dose packaging is intact.*

The Attorney General and the Board believe this to say that only drugs in original sealed tamper-evident packaging can be donated. The Attorney General and the Board interpret the intent of the statute as to permit the donation of drugs that had been prepackaged or repackaged by a pharmacy and dispensed to nursing homes.

Mr. Johnston said that the rule writing process involved contacting all the free clinics by phone and in writing, requesting information on policy, procedure and formularies. **Mr. Johnston** noted that the free clinics are not licensed by the Board but act as a dispensing physician's office outside of the auspices of the Board. A survey was sent out as well as a visit request form. Six clinics

returned the initial paperwork and visitations were made by the Board. Two of those six did not dispense drugs. The Board listened to comments, reviewed what other states had done both in statute and rule and drafted the rule. The language of that draft was revised at several subsequent meetings, incorporating dozens of changes, suggestions and restrictions. The proposed rule was submitted to the Department of Administration for publication in October, opening up the twenty-one day public comment period. Seven pieces of public comment were received; it seemed apparent the free clinics were working in conjunction with each other in providing valuable feedback. No other states had recognized nurse practitioners or physicians' assistants as volunteers in clinics having certain rights, which was an excellent public comment and an oversight that was incorporated into the rulemaking. Language for the pending rule was distributed, but additional issues were raised. Therefore, the pending rule was not published in the December bulletin as originally planned.

The Board then worked with **Representative Block** with regard to comments coming in after the public comment period closed. One great comment received was that the term "nurse practitioner" is not the correct term; rather, the correct term is "advanced practice professional nurse with prescriptive authority." **Representative Chew** submitted further comments, after which many additional comments came flooding in, arriving outside the public comment period specified in the Administrative Procedures Act. If the Board incorporated these comments, the entire rulemaking process could possibly be jeopardized.

Mr. Johnston distributed a copy of the withdrawn pending rule to the subcommittee, a copy of which is available at the Legislative Services Office (LSO). He clarified that the Board has approved the proposed changes contained in the withdrawn pending rule based on the comments timely received. **Mr. Johnston** distributed another copy of the rule with red-lined items that reflected changes based on comments received after the close of the comment period. This red-lined draft has not been approved by the Board. A copy of the red-lined draft is attached to these minutes. **Mr. Johnston** believes that this red-lined draft contains changes that the Board may be amenable to considering, but the Board members certainly vote on their own.

Mr. Johnston said that the Board is adamant about its belief that pharmacists are the only health care providers trained to identify contamination and adulteration, a task so important that statute specifically mentions it twice. There is some disagreement amongst clinics over formulary issues. Although there was disagreement among the clinics, the Garden City Clinic, with a decade of experience, is adamant that some control is needed against being the "dumping grounds" for physicians' waste. **Mr. Johnston** stood for questions.

Representative Nielsen asked if once donated drugs were received and checked before redistribution, as provided in section 380.03.b of the red-lined draft, can it be assumed correctly that the drugs are as good as any not donated. **Mr. Johnston** said that certainly a pharmacist should check for adulteration, etc. However, when manufacturers donate a product that has never been dispensed or in public hands, the Board is convinced that a lower level of scrutiny can be

permitted. Thus, the red-lined draft states that any volunteer can receive that product under the direct supervision of one of the practitioners listed.

Mr. Johnston stated that donated products that have been previously dispensed, mainly from nursing homes, create complications in the rulemaking. Labeling of such products must be checked by a pharmacist, making sure it is what it purports to be, since nurses, via statute, have the ability to repackage drugs within nursing homes. He emphasized that adulteration is not always visible; drugs exposed to sunlight can degrade faster than the listed expiration date and is nearly impossible to see.

Senator Broadsword asked whether the red-lined draft language for the pending rule incorporated responses from public comments, and whether this language necessitated the extension of the comment period referred to by **Mr. Stevenson**. **Mr. Johnston** said that if the Board extended the public comment period as suggested, he would assume that the red-line draft will take care of many issues that arose after the official public comment period, realizing that the red-lined draft has not yet been approved by the Board. **Mr. Johnston** said that if another official comment period is allowed in January, he would have to assume that additional comments would be received, so this draft pending rule may not be the final version. **Senator Broadsword** expressed her appreciation for the efforts and frustration with regard to this particular rulemaking.

Representative Nielsen asked if professionals dispensing donated drugs would be willing to take that medicine under the scrutiny of this rule. **Senator Broadsword** said her concern is that, now the law is in place, the rule seeks to deal with all safety factors, believing **Representative Nielsen**'s question was addressed during actual adoption of statute.

Senator Bock said that one's willingness to take donated drugs is not the issue, but rather the issue is what procedural safeguards are in place. He believes any person should not be put in the position of wondering whether a donated drug is safe, believing that compromises can be found to allow the donation of drugs while ensuring their safety.

Representative Chew replied to **Representative Nielsen**'s question by saying that she worked in a free clinic for six years, and she would be very willing to take donated drugs. Bubble packs being referred to have been examined by a pharmacist so she would be very comfortable taking donated drugs herself.

Representative Block asked **Mr. Johnston** why the Board did not use the negotiated rulemaking process for this rulemaking. **Mr. Johnston** said this was a very good question; the Board felt that the lengths gone through to informally negotiate by contacting free clinics via phone and in writing numerous times went beyond what the posting of a public hearing in a bulletin would have provided. Because these are free clinics staffed largely with volunteers, the Board was not sure how many would come to Boise for a hearing. The Board believed that the number of clinics contacted represented a larger number of clinics. In retrospect, **Mr. Johnston** said that in the future when a statute mandates that the Board write a set of rules, all political avenues need to be

utilized, including perhaps formal negotiations. He said that in conversations with **Mr. Stevenson**, this is not practical, from a time and expense perspective, on every set of rules.

Senator Bock referred to the statute, asking for copies, which were quickly obtained and handed out.

Representative Block said she has found that negotiated rulemaking does streamline the process. In cases where there may be some necessity for getting input from many parties, negotiated rulemaking is very helpful and the subcommittee would appreciate that being done in the future.

Representative Nielsen referred to section 380.05.e of the red-lined draft, " . . . dispensing donated drugs are required to provide patient counseling," and asked if patient counseling is required if the drug is not donated and, if so, whether that is consistent. **Mr. Johnston** answered that patient counseling is required by statute and is done with every new prescription, although perhaps not on a refill. The Board would expect that all new prescriptions would be counseled.

Representative Nielsen referred to section 380.06.a of the red-lined draft, "Legend drugs donated under these rules must not be . . . transferred to another charitable clinic or center," and asked if there are excess drugs at one clinic or center and another clinic needed those drugs, could drugs be transferred between clinics to prevent waste. **Mr. Johnston** answered that this provision is similar to that found in other states. There is great concern about counterfeit drugs entering normal distribution channels and that is why the Wholesale Drug Distribution Act was passed in 2007 to tightly regulate this area of distribution. The Legend Drug Donation Act, enacted in 2009, exempts anything to do with the 2007 Act. Any time a transaction takes place outside the normal distribution channel by our own state statute, the Board believes there needs to be more supervision.

Representative Nielsen said this did not answer his question; are excess usable drugs allowed to go to another clinic or center or are they destroyed simply because there is no legal and safe way to move those excess drugs from point A to point B. **Mr. Johnston** replied that the short answer is "this is correct." The statute has created safety measure for pharmacies, wholesalers, doctors, etc. The Board does not have the ability to inspect, investigate or walk into clinics to do documentation since free clinics are not overseen by the Board. There are dangerous drugs being dealt with, and very serious considerations are necessary.

Representative Nielsen asked if a charitable clinic has excess usable drugs, could other charitable clinics be notified so that patients could get them from the clinic having such excess drugs. **Mr. Johnston** said that would be a great work-around.

Senator Bock said the theme of this meeting may be the requirement that the donated drugs be subject to counseling by a pharmacist. He looks at free clinics as being essentially a doctor's office. Many sample prescription drugs are channeled through physician offices and are never subject to inspections or counseling by a pharmacist. It seems to him that the proposed rules go

beyond many procedures customarily followed within physician offices. **Mr. Johnston** responded that statute lists two forms of charitable clinics or centers, those with or without a pharmacy. If rules are written to pertain to non-pharmacy entities, then the full statutory concern is not being addressed. The issue is complex and complicated. He is not an expert in the Board of Medicine rules or statute, but is not aware of a statute requiring a physician to counsel a patient in medication use. He believes that if a sample is distributed by a physician, there is counseling by that physician, although such counseling may not be required by statute.

Representative Rusche said that as a licensee of the Board of Medicine, drug counseling is a standard of the physician profession. Many physician offices may not fill out forms with regard to the acceptance or rejection of counseling on drugs, but samples are distributed with explanations, including side effects. **Mr. Johnston** said that the red-lined draft at section 380.07.b does not require that a counseling log be kept. With regard to the situation described by **Senator Bock**, **Mr. Johnston** stated that counseling is not required by the pharmacy statute or rule but is a private business practice designed to protect the pharmacist.

Representative Block asked if drug counseling at a free clinic would be the same as private physician counseling. **Mr. Johnston** said there is sometimes purposefulness in being vague and this is one of those areas; the expectation is always that a physician would counsel a patient, leaving that definition up to the physician as to what that physician believes is appropriate.

Representative Block opened the meeting to public testimony.

Representative Sue Chew testified that as a pharmacist, she has been very mindful of the public safety, while at the same time supporting free clinics to function and serve the public. She said that a pharmacist will testify regarding the important role served by nurses in allowing pharmacists to do their jobs fully. Someone will also testify from a clinic about the role of nurses in checking medications for adulteration or misbranding.

Former Representative Margaret Henbest said she has been directly in touch with the Board about her concerns. What should be addressed at this meeting is the legality of the process. Rather than making additional comments, she is supportive of postponing publication of the Board's rules until the February bulletin as recommended by **Mr. Stevenson**.

Mr. Allen Frisk, Capital Pharmacy Association, Boise, Idaho, testified via telephone conference call, saying that he hated to see medications go to waste if others can use them, of course with safety considerations. He has been in the pharmacy business for 40 years and has spent 35 of those years in institutional settings in Idaho, including hospitals and nursing homes. He appreciated the testimony by **Mr. Johnston** and the efforts by the Board to strictly regulate for safety of the public. He said he personally would take donated medications. **Mr. Frisk** stated that efforts must be made to keep medications out of land fills and the water ways. Advanced practitioners can handle drugs safely in the absence of a pharmacist. He said that drugs come to nursing homes from many sources and, in the absence of a pharmacist, professionals are required

to go through a training program to ensure patient safety. He said that safety features are in place, and there is awareness of keeping drugs in proper, safe environments.

Ms. Pat Lazare commended the germane joint subcommittee for their extraordinary efforts and deferred to testimony already presented.

Mr. Steven Reames, Executive Director, Genesis World Mission, has operated the Garden City Community Clinic since 2002. He stated that a large part of the Garden City clinic's operation includes prescribing medications at no charge to uninsured patients, many with incomes at less than twice the federal poverty guidelines. Last year, the clinic administered $665,000 worth of medication. The clinic has three sources for medications: (1) drugs purchased at wholesale cost, (2) drugs donated by pharmaceutical representatives, and (3) drugs procured directly through an application process to the manufacturer, which are then mailed directly to the clinic. **Mr. Reames** said that during the public comment period and the ensuing conversations with the Board, the clinic attempted to work with the Board to fashion rules to serve the public interest as well as meet the needs of the clinics. He expressed appreciation to **Mr. Johnston** for taking into consideration many of those comments and for his work in this rulemaking process. However, he does take issue with section 380.03.a in the red-lined draft:

> Donated drugs may be received at a charitable clinic or center only at times when a licensed pharmacist, physician, physician assistant, or advanced practice professional nurse with prescriptive authority is present. Alternatively, a donating entity may place donated drugs in a double locking, permanent fixture, located within the charitable clinic or center, as approved by the Board.

Mr. Reames understands this red-lined draft has not yet been approved by the Board. The problem is that he believes that this is a very impractical rule under the circumstance in which free clinics operate. Usually, non-medical staff are present at the clinic most of the week, spending their time arranging for the very few focused hours that medical staff are actually present to serve the public. Those very focused hours are spent by the professionals caring for patients. Requiring a medical provider or pharmacist to be present when drugs are actually received in the clinic will take away the opportunity for patient care, an unnecessary diversion. It is often necessary for clinic personnel to work in the medication closet, receiving drugs from pharmaceutical companies and putting away ordered stock and appropriate donations. This storage closet is very well organized, 100 square feet in size, monitored by a camera and secured separately. If this rule as written in draft is implemented, it would force medical staff to take time away from patients to perform administrative functions done easily by trained staff. Many free clinics function during evening hours, and this would be a very inconvenient time for donating entities to make drug donations.

The proposed rule references a lock-box. Insulin must be received and stored in a cooler. Under current proposed administrative rules, **Mr. Reames** said he would be breaking the law by signing for that insulin and putting that into a refrigerated stock room without a pharmacist, physician or

other licensed practitioner present. He believes this draft pending rule is restrictive and very unworkable. The Garden City clinic is the largest free clinic in the state with more resources than many smaller clinics that have fewer staff and hours of operation. This is a major concern that was raised during the public comment period.

Mr. Reames addressed the issue of offloading drugs to another clinic and perhaps having patients from one clinic picking up a donated drug from another clinic. This may be allowed for community health centers that have pharmacies in their facilities, but free clinics do not function as a pharmacy, but rather as a doctor's office using a sample closet. A patient would have to become a qualified patient of a clinic in order to receive drugs from that clinic. Based on public testimony, **Mr. Reames** said the intent was for donated drugs to benefit others, but complications have arisen. The statute allowed prepackaged drugs to be legally donated, but the administrative rules, as proposed, are unrealistic.

Representative Rusche asked if it was **Mr. Reame's** position that there is no need for a licensed individual to be involved with these donated medications. **Mr. Reames** answered that his clinic has functioned very successfully with trained personnel under the direct general supervision of a medical practitioner; under these circumstances, the clinic has been well equipped to receive, secure and inventory these drugs safely and to also meet the functional needs of the clinic.

Representative Rusche asked if the Garden City Clinic has direct supervision of a physician's assistant, noting that the draft pending rule states that a licensed medical professional must be present. **Mr. Reames** said that during the week the clinic is open for administrative functions to receive mail, drugs and sample medications, but most of the time no licensed practitioner or pharmacist is present. Staff or volunteers are trained to perform the function of receiving donated drugs, but a medical provider is not on-site, except during limited clinic hours of about 12-16 hours weekly. There is no set delivery times. Coordinating receipt of drugs with a medical professional present would be difficult. Donated drugs should be examined, but the receipt of the drugs and securing the drugs for later examination could not be legally done under these administrative rules.

Representative Rusche asked how drugs donated by a nursing home are treated. **Mr. Reames** answered that all drug donations received are not put directly into stock, if there is not a professional present, but are put in a secure place until further examination can take place. **Representative Rusche** then asked about a lock-box. **Mr. Reames** said there is concern regarding cost and workability of a lock-box, refrigeration, after-hours deliveries and other logistical matters. He has not had the time to work with the Board about these technicalities. **Representative Rusche** expressed concern about repackaged drugs not being examined by a professional. **Mr. Reames** acknowledged that concern is valid.

Representative Nielsen also expressed concern about section 380.03.a of the red-lined draft, "a donating entity may place donated drugs in a double locking, permanent fixture, located within the charitable clinic or center, as approved by the Board," meaning to him that the person donating

has to put drugs in a lock-box. If drugs come via mail or other means, that may be difficult. He wondered if arrangements could be made for drugs to be placed in a lock-box to be inspected later by a pharmacist. **Mr. Johnston** said this lock-box language was developed the prior day and the key phrase is "as approved by the Board." He is not a proponent of tasking his inspectors with additional duties when already stretched thin, but he agreed that if drugs arrive via mail, a donee cannot place those drugs in a lock-box.

Representative Block thanked **Mr. Johnston** for all his hard work and collaboration. She affirmed that everyone wants to work together so free clinics can continue to provide valuable services and that the rules provide necessary oversight and safety precautions.

Senator Broadsword asked **Mr. Johnston** about the definition of a donated drug, and if exempting drugs donated by pharmaceuticals or physicians would solve some problems for clinics. **Mr. Johnston** responded that this is a complicating factor, and there should be a different level of scrutiny for products not in the original manufacturer sealed tamper-evident packaging that come directly from manufacturers, wholesalers or hospitals versus a drug repackaged and dispensed by a pharmacist and then, perhaps repackaged again by a nurse. Perhaps the best way would be to alter the statute to eliminate manufacturers from this process altogether. **Mr. Johnston** believes statute was crafted with the thought that nursing homes would be a donating entity, necessitating higher scrutiny. Having donating entities listed as manufacturers, wholesalers, etc. has complicated things and perhaps isn't necessary since that mandates a further level of regulation upon a practice where problems did not exist in the past. **Senator Broadsword** said that it is a bigger concern to mess with something that works. She doesn't want to stop the current practice of pharmaceutical companies donating drugs to free clinics. An amendment to the current statute might be best so as to not harm what is currently working.

Senator Bock thinks that the rules need to anticipate changes in the statute that are problematic. He suggested that the Legislature work in concert with the Board to develop the rules that will recognize that the statute could be or will be amended to reflect these legitimate concerns. **Mr. Johnston** said that nearly every section of this rulemaking is affected by the different levels of scrutiny required of the different donating entities. He estimated that perhaps half of these rules could be eliminated if statute was clarified. He asked **Mr. Stevenson** if there was a way to amend the statute and then amend the rules or adopt the rules and then change them after the statute is changed.

Mr. Stevenson clarified that normally something is put into rule that is not authorized by statute. The normal procedure is to first amend the statute. Agencies are cautioned to not run rules at the same time as proposing legislation that the rule is based upon. If the legislation fails, the rule is then invalidated.

Senator Bock said that the rule being discussed does not address particular issues raised by statute. There has been testimony that rule does not implement statute. The rule could be drafted in anticipation of a statutory change but not put into effect until after the statutory change has been

adopted. **Mr. Stevenson** answered that it would not be unusual to have a rule on the books that is not necessarily enforced.

Representative Nielsen said that a process is in place whereby the statute could be changed and a temporary rule could be developed to fit that changed statute.

Senator Broadsword worried that over 400 man hours may be wasted if a temporary rule is adopted. **Mr. Johnston** said that if the statute needs to be changed, perhaps the proposed pending rule should be withdrawn pending the corrective legislation followed by a temporary rule that addresses that legislation with a new pending rule to be submitted to the 2011 Legislature. **Mr. Stevenson** said that would be a valid approach; the proposed rule could be vacated, and if the statute was amended, a temporary rule could be adopted. Alternatively, the Board could proceed with a pending rule at this time and amend it following the adoption of any corrective legislation. This would put something into place. **Mr. Stevenson** cautioned that people prefer not to operate under a temporary rule, if unnecessary.

Senator Bock asked if **Mr. Stevenson** agreed with his proposal to proceed with a rule that does not implement all parts of the statute. **Mr. Johnston** said his understanding of the rule process is that rules that go through the usual channel would be in effect at end of the legislative session. An emergency rule would could go into effect immediately, before the end of the legislative session, so it would be quicker to go the emergency route. **Mr. Stevenson** responded that he did agree with that. **Representative Nielsen** commented that such an approach would not lose time.

Ms. Dawn Weiler, Medical Director at the Friendship Clinic in Boise, thanked the Board for its hard work on this challenging and frustrating rule. She stated that the Friendship Clinic is staffed one night a week, wholly by volunteers. **Ms. Weiler** addressed section 380.03.e of the red-lined draft relating to medications previously dispensed and then donated to clinics and the process for ensuring public safety. The proposed rule requires that the verification and identification must be done by only a licensed pharmacist before going into a clinic's distribution supply. **Ms. Weiler's** concern is that as a very small free clinic, the Friendship Clinic does not have a pharmacist present who can do a visual inspection. She stated that a nurse is capable of performing a visual inspection. She recommended that other advanced practice level practitioners, physician assistants, etc. be included in this portion of the rule.

Senator Bock asked if the red-line changes in the draft pending rule addressed her concerns, and **Ms. Weiler** said they do not since section 380.03.e states that inspections must be performed by "a licensed pharmacist."

Senator Broadsword asked if **Ms. Weiler** sent in comments during the public comment period. **Ms. Weiler** answered "yes," adding that subsequent comments have also been submitted. **Ms. Weiler** stated that the Friendship Clinic never personally received the mailings from the Board.

Representative Rusche asked what percentage of the drugs donated to the Friendship Clinic would fall into the category of requiring a licensed pharmacist to examine and what percent would be exempt, being in original packaging. **Ms. Weiler** said at this point donated drugs are only being accepted from manufacturers pending these rules.

Mr. Johnston said the Board believes that pharmacists are the only ones who have received adequate training to identify adulteration, having seen very clever tactics in this area. He has no evidence of organized training in this area other than by pharmacy schools. The Board is adamant in protecting the public safety, and this one piece should be reserved for only pharmacists. He pointed out the red-line draft pending rule backs off on any product in original manufacturers tamper-evident sealed packaging, and applies the inspection requirement only to drugs previously dispensed.

Ms. Weiler said it must be remembered that, in reality, the vast majority of the donated drugs will be blood pressure or diabetes medications, typically not drugs targeted for common diversion. She wants only the best and safest medications for the clinic and its patients; if she needs to take drugs to a pharmacist to be reviewed, she is not sure whether increasing the risk of damage or misplacement is the greater of two evils.

Senator Bock said that physicians are currently volunteering at free clinics and asked whether there is a program that could be implemented to encourage pharmacists to provide the services required to verify the drugs. He observed that suggestion is obviously outside this rulemaking process. **Mr. Johnston** said there are pharmacists in Idaho who cannot find work, so it is easier now to find a pharmacist to participate at free clinics. However, he reiterated that it is necessary for a pharmacist to perform these inspections for public safety.

Ms. Weiler asked what in these inspections is outside the scope of other professionals. **Mr. Johnston** replied that a month ago he requested proof of training of health care professionals in adulteration to be considered by the Board, but no proof of training in adulteration has been received from other health care professionals. The Board has received statements of belief, but not proof.

Ms. Sandra Evans, Executive Director, Board of Nursing, stated that she did not come to the hearing to comment on the rule and that the Board of Nursing did not provide comments during the comment period. Recently, the Board of Nursing was contacted and asked to provide information on the scope of practice for advance practice professional nurses with prescriptive authority and for other nurses in some functions being suggested under the proposed changes to this rule. **Ms. Evans** submitted her comments in writing to the subcommittee, which are available at LSO. Her letter suggested that the term "nurse practitioner" be changed throughout the docket to read "advanced practice professional nurse with prescriptive authorization." This suggestion has been incorporated into section 380.02.a of the red-lined draft. Regarding section 380.03.e of the red-lined draft, **Ms. Evans** commented that nurses have historically been the last safety net before drugs are administered to patients and, as such, examined drugs for alteration.

Senator Bock asked **Ms. Evans** to identify the standards for review or training received by nurses to ensure that drug donations are being properly examined and whether the Board of Nursing has such a training program that might satisfy the Board of Pharmacy. **Ms. Evans** answered that the Board of Nursing does not have rules governing these issues. She deferred to the educational programs for both basic nursing and advance practice nursing and does not know if this would satisfy the Board of Pharmacy.

Ms. Evans concluded by saying that after review of the statute and rule, the Board of Nursing is confident that suggested changes in the red-line draft are consistent with the legally defined scope of practice of nurses found in Board of Nursing rule and through the review of educational preparation required for advance practice nurses in particular.

Dr. McClusky, Mustard Tree Clinic, Twin Falls, Idaho (via telephone conference call) was called to surgery and was unable to testify but expressed his appreciation at being allowed to listen to the meeting by phone.

Representative Rusche asked **Ms. Evans** when nurses examine and assess medications, are the drugs usually ones previously prescribed and prepared for a particular patient. **Ms. Evans** answered that previously dispensed and prepared medications unfortunately can be tampered with by existing staff or other persons in a facility, so nurses do examine medications.

Representative Rusche expressed his appreciation to the Board of Pharmacy for the hard work done on this rule; he understands also the role of free clinics and he believes it is necessary to fulfill the requirements of both the Board and the clinics through flexibility. He looks forward to seeing the final result of this rulemaking process. To him, the most expeditious process is to allow an extended comment period and then request the Speaker and the Pro Tem to allow a hearing on the pending rule once it has been published in the February bulletin.

Senator McGee said it sounded like all testimony had now been heard and asked if **Representative Rusche** had made a motion. **Representative Rusche** said he would not mind his comments being considered to be a motion wondering if it is beyond the subcommittee's scope to direct the Board to reopen the rulemaking process. He believes that the pending red-line rule draft was a successful attempt by the Board. He asked if it would be appropriate for the subcommittee to ask the Board to publish rules later at the end of February, rather than in January.

Representative Block allowed **Paige Alan Parker** to comment. **Mr. Parker** said that statute doesn't provide a lot of procedural guidance, but it does say that the formal action of the subcommittee, with appropriate majorities, is to adopt an objection or, if no objection, so state and report back to the Legislature and to the agency (Board of Pharmacy). Within that language, a report could include a recommendation, believing statute to be broad enough to allow this germane joint subcommittee to make a recommendation in its report.

Representative Rusche moved that the subcommittee not accept the originally published rule and that the subcommittee recommend to the Board of Pharmacy that the comment period be reopened and bring a new set of rules.

Mr. Stevenson said this could not really be done because in this scenario, there would be publication of two proposed rules in the same rulemaking. This current rule would have to be vacated and a new rulemaking would have to be started in order to accomplish **Representative Rusche's** motion. The other scenario would be for this subcommittee to object to the rule, but that doesn't carry a lot of weight as far as what is going to happen in the current process, but does make a difference in the review process where the rule could be rejected. If the comment period was extended, this rulemaking could go forward as a pending rule, assuming that most objections would be satisfied.

Senator Broadsword moved that the Germane Joint Subcommittee not object to Docket No. 27-0101-0904, to encourage the Board of Pharmacy to continue working on this rulemaking docket, to encourage the Board of Pharmacy to reopen the public comment period on this rulemaking docket, and to request Pro Tem Geddes and Speaker Denney to allow flexibility in the rule review process during the 2010 legislative session so that this rulemaking docket may be reviewed by the Senate and House of Representatives Health and Welfare Committees as a pending rule following its anticipated publication in February 2010. Representative Rusche withdrew his original motion and seconded Senator Broadsword's motion.

Senator Bock said the motion now reflects what is the consensus blueprint in moving forward, which will likely include amendment of statute in order to eliminate one problematic area.

Senator Broadsword expressed her appreciation to the Board for its hard work on this rulemaking and in attempting to appease all parties. She encouraged the Board to move forward.

Representative Nielsen commented that this is a new area where new procedural rules seek to implement a statute that allows clinics to use donated drugs and that "a home run cannot occur on first try." He is very supportive of all discussion and encourages the Board to go forward because progress is being made.

Representative Block said that concern has been expressed by physicians who donate samples about the need to document on a manifest information about the samples. The concern is that this will deter physicians from donating because they don't have the time for such documentation or may be held liable in the future for how donated drugs might be used or misused. Many free clinics rely on drugs donated by physicians, and he asked that this be considered by the Board.

Mr. Johnston said that curiously, physicians, nurse practitioners and others are not donating entities under the rule, so while the statute was crafted to allow previously dispensed drugs from nursing homes to be donated and while the statute may have inadvertently included wholesalers and manufacturers, it doesn't regulate physicians or samples donated by physicians. **Representative Block** said this may be an issue that needs to be addressed in statute.

Senator Broadsword's motion was voted on and passed unanimously by voice vote.

Mr. Parker stated he would prepare a report on behalf of the subcommittee, including the motion. The report will go to the Pro Tem, the Speaker, the Senate and House Health & Welfare Committee members and the Board of Pharmacy.

Mr. Johnston said he would like to give rebuttal to **Mr. Reame's** comments with regard to refrigeration of donated drugs. The Board is extremely concerned about secure storage of drugs and, in the absence of a health care provider, allowing access to a locked storage area where all medications are stored does not protect the public safety. Clinic volunteers are in an unregulated facility; the Board does not have inspection or enforcement rights with regard to these clinics. Certainly, a technician or a store manager would never be allowed in a pharmacy without presence of a pharmacist. **Mr. Johnston** agreed that **Mr. Reame's** clinic is very organized, more so than many free clinics. He knows this creates a problem for donating, believing that a lock-box could solve this dilemma, although the definition of a lock-box has yet to be developed. Receipt of drugs during off-hours is most concerning to the Board in its regard for public safety. **Senator Bock** said that based on the tenor of the discussion today, this is the sort of problem that can be resolved.

Representative Block thanked everyone for participating in this meeting. She said that the clinics are providing a very needed community service and free clinics need to be viable and continued. She thanked the Board of Pharmacy and all the meeting participants, recognizing the important public safety concerns. She expressed hope that issues can be worked out either through statute or rulemaking. She thanked everyone for working together so collaboratively thus far.

The meeting was adjourned at 12:50 p.m.

Attachment: Draft of Red-lined Pending Board of Pharmacy Rule

IDAPA 27
TITLE 01
CHAPTER 01

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

366. -- ~~400~~379. (RESERVED).

380. LEGEND DRUG DONATION – STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. In order to be eligible for donation, drugs must meet the following criteria: ( )

a. The drug name, strength, lot number, and expiration date must appear on the drug package or label. ( )

b. Donated drugs must be approved by the federal Food and Drug Administration and: ( )

i. Be ~~sealed~~ in the ~~manufacturer's unopened~~ original, sealed, tamper-evident packaging and either: ( )

(1) Individually packaged, or ( )

(2) Packaged in unit-dose packaging; ( )

ii. Be oral or parenteral drugs in sealed single-dose containers approved by the federal Food and Drug Administration; ( )

iii. Be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or ( )

iv. Be parenteral drugs in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn. ( )

c. Donated drugs must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug wholesaler or manufacturer. ( )

d. Donated drugs ~~must not require~~ requiring storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, ~~because of the potential for these drugs to become adulterated~~ may only be donated by the manufacturer of the drug, wholesale distributor of the drug, hospitals or pharmacies. ( )

e. Donated drugs must not be the subject of federal Food and Drug Administration restricted drug distribution programs, including but not limited to thalidomide and lenalidomide. ( )

02. Donation Standards. ( )

a. The licensed pharmacist, advanced practice professional nurse with prescriptive authority, or physician at the charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. ( )

b. Donating entities may only donate drugs that appear on the charitable clinic or center's formulary. ( )

c. A licensed pharmacist, nurse, or physician from the donating entity must sign and date a manifest before delivery of the donated drugs to the charitable clinic or center that: ( )

i. Certifies that the donated drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and the United States Pharmacopoeia standards; ( )

ii. Certifies that the donated drugs have been continuously under control of a health care professional and have never been in the custody of a patient or other individual; ( )

iii. Certifies that the donating entity has only donated drugs on the charitable clinic or center's formulary; ( )

iv. Certifies that the donating entity has complied with the provisions of these rules; ( )

v. Certifies that the patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the donating entity; ( )

vi. Lists the names of the donating entity and the name of the receiving charitable clinic or center; and ( )

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug to be donated. ( )

d. A copy of the manifest must be delivered to the charitable clinic or center with the donated drugs. ( )

03. Receipt of Donated Drugs. ( )

a. Donated drugs may be received at a charitable clinic or center only at times when ~~A~~ a licensed pharmacist ~~must verify that donated drugs meet the criteria in Subsection 380.01 of these rules, and upon receipt must:~~, physician, physician assistant, or advanced practice professional nurse with prescriptive authority is present. Alternatively, a donating entity may place donated drugs in a double locking, permanent fixture, located within the charitable clinic or center, as approved by the Board. ( )

~~i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the drug name and strength noted on the label of each unit of the packaged, donated drug is correct; and~~ ( )

~~ii. Determine that donated drugs are not adulterated or misbranded and are safe to dispense.~~ ( )

~~**b.** Improperly donated drugs that do not meet criteria in Subsections 380.01 or 380.03 of these rules must be destroyed, and documentation of such destruction must be maintained within a destruction record.~~ ( )

~~c~~b. ~~A licensed pharmacist at the charitable clinic or center must document receipt of each d~~Donated drugs must be verified on each manifest and may be verified by any individual working at the clinic provided that the individual is supervised by a pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority. ( )

~~d~~c. In the event that the identifying patient information is not removed by the donating entity, ~~the~~ a licensed pharmacist, physician, physician assistant, or advanced practice professional nurse with prescriptive authroity at the charitable clinic or center must remove or redact that information. ( )

d. Before being re-dispensed to indigent patients, a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must verify that donated drugs meet the criteria in Subsection 380.01 of these rules. ( )

e. For the following donated drugs only, before being re-dispensed to indigent patients, a licensed pharmacist must verify utilizing a current drug identification book, a computer program, or an online service for the same that the drug name and strength noted on the label of each unit of the packaged, donated drug is correct and determine that donated drugs are not adulterated or misbranded and are safe to dispense: ( )

i. Donated drugs that have been previously dispensed, ( )

ii. Donated drugs that are not in the manufacturer's original, sealed, tamper-evident packaging, and ( )

iii. Drugs donated from a nursing home. ( )

f. Improperly donated drugs that do not meet criteria in Subsections 380.01 or 380.03 of thse rules must be destroyed, and documentation of such destruction must be maintained within a destruction record. ( )

04. Storage of Donated Drugs. ( )

a. Drug storage must have proper environmental controls to assure the integrity of the drug in accordance with the drug manufacturer's recommendations and United States Pharmacopoeia standards. ( )

b. Donated drugs may be commingled with the charitable clinic or center's regular stock of drugs only if the packaging on the donated drugs has been labeled to show that the drugs were obtained through a donating entity. ( )

c. Donated drugs with packaging that has not been labeled to show that the drugs were obtained through a donating entity must be kept in an area that is separately designated from the charitable clinic or center's regular stock of drugs. ( )

d. The space in which drugs are stored must be locked at all times except during operating hours or other time when a licensed pharmacist, ~~or~~ physician, physician assistant, or advanced practice professional nurse with prescriptive authority is physically present in the charitable clinic or center. ( )

05. Dispensing Donated Drugs to Medically Indigent Patients. ( )

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions must not be re-dispensed to indigent patients and must be destroyed. Documentation of such destruction must be maintained within a destruction record. ( )

b. A pharmacist, ~~or~~ physician, physician assistant, or an advanced practice professional nurse with prescriptive authority working at a charitable clinic or center who re-dispenses donated drugs to any patient must: ( )

i. Utilize a proper and appropriate container; ( )

ii. Place a label on the container that conforms to provisions of these rules; and ( )

iii. Initial the prescription label. ( )

c. The re-dispensed drug must be assigned the same expiration date as is on the original package. ( )

d. A charitable clinic or center must maintain dispensing records for each donated drug dispensed. ( )

e. Pharmacists, ~~or~~ physicians, physician assistants, and advanced practice professional nurses with prescriptive authority dispensing donated drugs are required to provide patient counseling. ( )

06. Miscellaneous. ( )

~~**a.** A licensed pharmacist or physician must be on duty during all hours of operation of the charitable clinic or center. ( )~~

~~**b**~~**a**. Legend drugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. ( )

~~**c**~~**b**. Nothing in these rules precludes a charitable clinic or center from charging an indigent patient a dispensing fee. ( )

07. Record Keeping Requirements. ( )

a. Donating entities must maintain all manifests in a readily retrievable fashion for at least two (2) years. ( )

b. Charitable clinics or centers must maintain destruction records, dispensing records, and manifests in a readily retrievable fashion for at least two (2) years. ( )

381. -- 400. (RESERVED).

AGENDA

BOARD OF PHARMACY
RULE MEETING

Tuesday, December 8, 2009
10:30 a.m.

LEN B. JORDAN BUILDING
650 W. STATE STREET
CLEAR WATERS CONFERENCE ROOM
THIRD FLOOR - ROOM #302

10:30 a.m.	**Opening remarks by the Chair**
10:35 a.m.	**Comments by the Germane Subcommittee members**
11:05 a.m.	**Presentation of Docket #27-0101-0904 by Mark Johnston, Executive Director, Board of Pharmacy and questions by the Subcommittee members**
	Comments from the public as permitted by the Chair with questions by the Subcommittee members
11:45 a.m.	**Discussion and vote by the Subcommittee members regarding possible objection to Docket #27-0101-0904**
12:00 p.m.	**Adjourn**

GERMANE JOINT SUBCOMMITTEE MEMBERS

Senator Patti Anne Lodge, Co-chair
Senator Joyce Broadsword
Senator Nicole LeFavour

Representative Sharon Block, Co-chair
Representative Pete Nielsen
Representative John Rusche

If you have questions, please contact Charmi Arregui at 334-4845 or Paige Alan Parker at 334-4857.

NOTICE OF MEETING

GERMANE SUBCOMMITTEE REVIEW OF IDAHO STATE BOARD OF PHARMACY RULE DOCKET #27-0101-0904 IDAHO LEGEND DRUG DONATION ACT

DECEMBER 8, 2009
10:30 a.m.
LEN B. JORDAN BUILDING
650 W. STATE ST.
CLEAR WATERS CONFERENCE ROOM
THIRD FLOOR

A copy of this rule and the analysis by
the Legislative Services Office
can be viewed at:

http://www.legislature.idaho.gov/sessioninfo/2009/Interim/adminrules/2701010904.pdf

GERMANE JOINT SUBCOMMITTEE
MEMBERS

Senator Patti Anne Lodge	Representative Sharon Block
Senator Joyce Broadsword	Representative Pete Nielsen
Senator Nicole LeFavour	Representative John Rusche

For questions please call Charmi Arregui at 334-4845 or
Paige Alan Parker at 334-4857

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Jeff Youtz
Director

November 13, 2009

Mark D. Johnston, Director
Board of Pharmacy
3380 Americana Terrace, Suite 320
P.O. Box 83720
Boise, ID 83720-0067
334-3536 (fax)
mark.johnston@bop.idaho.gov

Re: Germane Subcommittee review of Docket No. 27-0101-0904

Dear Director Johnston:

Pursuant to section 67-454, Idaho Code, two members of the Subcommittee of the Senate Health and Welfare Committee and the House Health and Welfare Committee have requested a meeting to review Docket No. 27-0101-0904, Rules of the Idaho State Board of Pharmacy. The meeting of the Subcommittee will be held in Boise, Idaho, on or before December 11, 2009, at a time and a place to be determined. You are requested to attend that meeting to discuss this rulemaking.

Sincerely,

Paige Alan Parker
Legislative Analyst

cc: Senators Patti Anne Lodge, Joyce Broadsword and Nicole LeFavour; Representatives Sharon Block, Pete Nielsen and John Rusche; and Dennis Stevenson, Administrative Rules Coordinator

Dear Senators LODGE, Broadsword & LeFavour, and
Representatives BLOCK, Nielsen & Rusche:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Board of Pharmacy:

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 11-13-09. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 12-11-09.

_____The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-2475, or send a written request to the address or FAX number indicated on the memorandum enclosed.

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Research & Legislation Staff - Paige Alan Parker

DATE: October 26, 2009

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908) (Proposed)

The Board of Pharmacy submits Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908 (hereinafter individually and collectively "proposed rule"), amending various provisions of the Board's chapter of rules found at IDAPA 27.01.01. The purpose of the rulemaking varies with the docket number. According to the Board:

> Docket No. 27-0101-0901 requires licensees to provide the Board with notice of any changes of name, address or telephone number within ten days.
>
> Docket No. 27-0101-0903 requires pharmacies to notify the Board in writing of their hours of operation and of any change in those hours at least 30 days prior to commencing new hours of operation.
>
> Docket No. 27-0101-0904 provides standards and procedures for the transfer, acceptance, storage, inspection, distribution and dispensing of donated drugs and provisions to enforce the Idaho Legend Drug Donation Act.
>
> Docket No. 27-0101-0905 allows pharmacists to provide up to a three-month supply of legend drugs that are not controlled substances, when a prescription is written for a smaller supply but includes refills sufficient to equal the larger supply.
>
> Docket No. 27-0101-0906 allows a pharmacist to provide pharmaceutical care outside a licensed pharmacy under certain conditions.

Docket No. 27-0101-0907 adds repackagers who are authorized distributors of record for Federal Drug Administration registered manufacturers to the definition of "normal distribution channel."

Docket No. 27-0101-0908 clarifies that a pharmacy may transfer a prescription to another pharmacy without first having to fill it and clarifies the record keeping responsibility of the receiving pharmacy.

According to the Board, the proposed rule is authorized pursuant to section 54-1717, Idaho Code. Chapter 17, title 54, Idaho Code, is the Idaho Pharmacy Act. Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy.

Additional authority available to the Board includes sections 37-2715, 54-1753 and 54-1763, Idaho Code. Chapter 27, title 37, Idaho Code is the Uniform Controlled Substances Act. Section 37-2715, Idaho Code, permits the Board to promulgate rules relating to the dispensing of controlled substances within Idaho. Section 54-1753(1), Idaho Code, requires every wholesale distributor who engages in wholesale distribution of prescription drugs to be licensed by the Board, with exceptions. Section 54-1763, Idaho Code, part of the Idaho Legend Drug Donation Act, requires the Board to adopt rules necessary for the implementation and enforcement of the program established under that Act and for the enforcement of Board rules promulgated thereunder.

According to the Board, no fee or charge is imposed by the proposed rule. The Board states that there is no anticipated impact to the general fund greater than $10,000 during the fiscal year as a result of the proposed rule. According to the Board, negotiated rulemaking was not conducted because of the simple nature of the rulemaking or, with respect to Docket No. 27-0101-0904, because negotiated rulemaking was not feasible, although Board staff did solicit information from charitable clinics to consider in developing the standards and procedures required by the Idaho Legend Drug Act.

The Board states that public hearing(s) will be scheduled if requested in writing by 25 persons, a political subdivision, or an agency, not later than October 21, 2009. All written comments must be delivered to the Board on or before October 28, 2009.

ANALYSIS

A. Docket No. 27-0101-0901

The proposed rule creates a new duty for every licensee and registrant to provide the Board with notice of any change to the licensee's or registrant's name, address or telephone number within ten days of the change. Section 142.03. The proposed rule also states that failure to fulfill any of the listed duties may constitute a violation of section 54-1726(a), Idaho Code, which permits the Board to refuse to issue or renew or to suspend, revoke or restrict a license for unprofessional conduct.

B. Docket No. 27-0101-0903

The proposed rule requires a pharmacy to notify the Board of the hours that it is open for business and requires notification to the Board of a desired change of hours at least 30 days prior to the change. Notification must be on a Board prescribed form. The proposed rule further requires that a pharmacy must prominently display and remain open during these hours with sufficient pharmacist staff during these hours. Section 180.08.

C. Docket No. 27-0101-0904

A new section 380 listing standards and procedures is provided by the proposed rule. In order for a drug to be eligible for donation, it must meet listed criteria dealing with identification, FDA approval and restriction, packaging, not subject to a recall and storage. Donation standards regarding responsibility, limitations on drugs eligible for donation, certification and listing requirements and copy requirements are stated. Verification, documentation and storage requirements are detailed. Limitations on what drug may be distributed to a medically indigent patient are prescribed as well as how such drugs are to be dispensed. Record keeping requirements are stated. Miscellaneous standards include the requirement that a licensed pharmacist or physician be on duty during all hours of operation of the charitable clinic or center and the prohibition on resale, trade or transfer of donated drugs. However, the proposed rule provides that an indigent may be charged a dispensing fee.

D. Docket No. 27-0101-0905

An exception to the unprofessional conduct section 184 allows a pharmacist, utilizing his best professional judgment, to provide up to a three-month supply of a legend drug that is not a controlled substance, when the practitioner has written a drug order to be filled with a smaller supply but includes refills in sufficient numbers to fill a three-month supply.

E. Docket No. 27-0101-0906

Section 165, regarding pharmaceutical care, is amended by the proposed rule to address pharmaceutical care by a licensed pharmacist outside a licensed pharmacy. Such independent practice is permitted if certain criteria regarding secure access to information and record keeping are collectively met.

F. Docket No. 27-0101-0907

This proposed rule modifies the definition of "normal distribution chain" to include within the chain of custody a prescription drug that goes from a manufacturer directly or through its co-licensed partner, third-party logistics provider or exclusive distributor to an authorized repackager whose facility is registered with the FDA and who engages in repackaging the original dosage in accordance with applicable FDA regulations and guidelines. Section 321.11.

G. Docket No. 27-0101-0908

The Board's rule regarding prescription transfer are amended by this proposed rule to describe that a receiving pharmacy that utilizes a computer prescription database that contains all of the prescription information required by law or rule must generate a hard copy to be treated as a new prescription. The proposed rule goes on to say that the pharmacy may enter the information required under the rule into its prescription database in lieu of writing the information on the hard copy of the prescription. Section 160.05. This rule appears to be contradictory.

SUMMARY

The Department's proposed rule change appears to be authorized under sections 54-1717, 37-2715, 54-1753(1) and 54-1763, Idaho Code.

cc: Idaho State Board of Pharmacy
Mark D. Johnston, Executive Director

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0901

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Current licensee contact information is essential to a successful regulatory process. The current Board of Pharmacy rules do not require licensees to provide updates on a timely basis. The proposed rules will amend the standards of conduct to require licensees to provide the Board with notice of any changes to the licensee's name, address, or telephone number within ten (10) business days from the date of any such change.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0901

142. ~~*STANDARDS OF CONDUCT*~~ PROFESSIONAL RESPONSIBILITIES.
A failure to fulfill any of the following duties may constitute a violation of Section 54-1726(a), Idaho Code.
( )

01. Duty to Cooperate in Investigation. It is the duty of every licensee and registrant to cooperate with a disciplinary investigation, and any failure or refusal to do so is grounds for disciplinary action. ~~*(4-6-05)*~~( )

02. Duty to Report Theft, Loss, or Adulteration. It is the duty of every pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances and any adulteration of any prescription drug to the Board, even if the theft, loss, or adulteration has been accounted for and the employee disciplined internally. The report of theft or loss, required hereunder, shall contain all of the information reported to the Drug Enforcement Administration (DEA), as required under 21 CFR 1301.74(c), and shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

03. Duty to Provide Current Contact Information. It is the duty of every licensee and registrant to provide the Board with notice of any change to the licensee's or registrant's name, address, or telephone number within ten (10) business days from the change. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0903

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rulemaking is necessary to alleviate any public safety issues that may be created by pharmacies not being open during their established hours of operation. The proposed rules will require pharmacies to notify the Board of Pharmacy in writing of their hours of operation and to notify the Board of any change in those hours at least thirty (30) days prior to commencing new hours of operation. The rules will require pharmacies to remain open during their stated hours of operation and to maintain sufficient staffing to ensure pharmacies are open during their stated business hours.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0903

180. DIFFERENTIAL HOURS.

01. Security at Pharmacy. A pharmacy must provide adequate security for its drug supplies, equipment, and records and in the absence of a pharmacist, the pharmacy must be closed. If a pharmacy is located within a larger business establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed by a partition, such as a glass or metal mesh screen or a security fence, that is sufficient to provide adequate security for the pharmacy, as approved by the Board or its representatives. In the absence of a pharmacist, the pharmacy must be locked. Employees of the business establishment may not be authorized to enter the closed pharmacy during those hours that the business establishment is open to the public for business. (7-1-93)

02. Equipment, Records, Drugs, and Other Items. All equipment and records referred to in these rules and all drugs, devices, poisons, and other items or products that are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area. (7-1-93)

03. Prescription Orders and Refill Requests. Written prescription orders and refill requests can be delivered to a pharmacy at any time. If no pharmacist is present, the prescription orders must be deposited by the patient, or his agent delivering the prescription order or refill request, into a "mail slot" or "drop box" that deposits the prescription order into the pharmacy area. The times that the pharmacy is open for business must be displayed in a manner that is prominently visible to the person depositing the prescription order. (7-1-93)

04. Storage of Prescriptions. Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place. (7-1-93)

05. Sale Restrictions. No drugs, devices, poisons, or other items or products that are restricted to sale either by or under the personal supervision of a pharmacist may be sold or delivered without a pharmacist being present in the pharmacy. (7-1-93)

06. Separate Telephone. Any pharmacy having hours differing from the remainder of a business shall have a separate and distinct telephone number from that of the business. The telephone shall not be answerable in the remainder of the establishment unless all telephone conversations during a pharmacist's absence are recorded and played back by the pharmacist. (7-1-93)

07. Oral Prescriptions. An oral prescription may not be accepted if the pharmacist is not present unless the prescription is taken on a recording that must inform the caller of the times the pharmacy is open. (7-1-93)

08. Hours Open for Business. A pharmacy must notify the Board, on a form prescribed by the Board, of the hours that the pharmacy is open for business. Any pharmacy desiring to change the hours that it is open for business, must notify the Board, on a form prescribed by the Board, at least thirty (30) days prior to commencing such hours. A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the hours it is open for business. A pharmacy must remain open for business the hours for which the Board has received such notification and that are prominently displayed. A pharmacy must maintain sufficient staffing by pharmacists in order to ensure that the pharmacy will be open during the hours of operation for which the pharmacy provided notice to the Board. If a pharmacy is located within a larger business establishment that has hours of operation different from the pharmacy, the hours the pharmacy is open for business shall be prominently displayed, in a permanent manner, at the pharmacy area and on, or adjacent to, the entrance to the mercantile establishment. ~~(7-1-93)~~( )

09. Advertising. Any advertising by the business establishment that references the pharmacy or products sold only in the pharmacy, and that includes the hours that the business establishment is open to the public for business, must also indicate the hours that the pharmacy is open to the public for business. (7-1-93)

10. Notification to the Board of Differential Hours. Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy, must notify the Board at least thirty (30) days prior to commencing such differential hours. To constitute notification, the applicant must complete and file the form provided by the Board with the required information. Board inspection and approval shall be completed prior to commencing differential hours. The inspection and approval or disapproval shall be completed within ten (10) days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and the pharmacy minimum standards set forth in Section 151 of these rules. (7-1-93)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0904

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The Idaho Legend Drug Donation Act requires the Board of Pharmacy to promulgate rules to develop and implement the program. The proposed rules will provide standards and procedures for the transfer, acceptance, and storage of donated drugs; for inspecting donated drugs; for distribution of donated drugs; for dispensing of donated drugs; and provisions to enforce the Idaho Legend Drug Donation Act.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted to seek consensus on the content of the rule.

The Idaho Legend Drug Act, which went into effect on July 1, 2009, mandated that the Board adopt rules necessary for implementation and enforcement of the program established by the Legislature, and listed five subject areas for which the Board was to adopt rules. Negotiated rulemaking was not feasible in this context. Board staff, however, did solicit information from charitable clinics to consider in developing the standards and procedures required by the statute.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720, Boise, ID 83720-0067
Phone: (208) 334-2356 / Fax: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0904

366. -- ~~400~~379. (RESERVED).

380. LEGEND DRUG DONATION – STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. In order to be eligible for donation, drugs must meet the following criteria: ( )

a. The drug name, strength, lot number, and expiration date must appear on the drug package or label. ( )

b. Donated drugs must be approved by the federal Food and Drug Administration and: ( )

i. Be sealed in the manufacturer's unopened original tamper-evident packaging and either: ( )

(1) Individually packaged, or ( )

(2) Packaged in unit-dose packaging; ( )

ii. Be oral or parenteral drugs in sealed single-dose containers approved by the federal Food and Drug Administration; ( )

iii. Be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or ( )

iv. Be parenteral drugs in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn. ( )

c. Donated drugs must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug wholesaler or manufacturer. ( )

d. Donated drugs must not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, because of the potential for these drugs to become adulterated. ( )

e. Donated drugs must not be the subject of federal Food and Drug Administration restricted drug distribution programs, including but not limited to thalidomide and lenalidomide. ( )

02. Donation Standards. ( )

a. The licensed pharmacist or physician at the charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. ( )

b. Donating entities may only donate drugs that appear on the charitable clinic or center's formulary. ( )

c. A licensed pharmacist, nurse, or physician from the donating entity must sign and date a manifest before delivery of the donated drugs to the charitable clinic or center that: ( )

i. Certifies that the drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and the United States Pharmacopoeia standards; ( )

ii. Certifies that the donated drugs have been continuously under control of a health care professional

and have never been in the custody of a patient or other individual; ( )

iii. Certifies that the donating entity has only donated drugs on the charitable clinic or center's formulary; ( )

iv. Certifies that the donating entity has complied with the provisions of these rules; ( )

v. Certifies that the patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the donating entity; ( )

vi. Lists the names of the donating entity and the name of the receiving charitable clinic or center; and ( )

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug to be donated. ( )

d. A copy of the manifest must be delivered to the charitable clinic or center with the donated drugs. ( )

03. Receipt of Donated Drugs. ( )

a. A licensed pharmacist must verify that donated drugs meet the criteria in Subsection 380.01 of these rules, and upon receipt must: ( )

i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the drug name and strength noted on the label of each unit of the packaged, donated drug is correct; and ( )

ii. Determine that donated drugs are not adulterated or misbranded and are safe to dispense. ( )

b. Improperly donated drugs that do not meet criteria in Subsections 380.01 or 380.03 of these rules must be destroyed, and documentation of such destruction must be maintained within a destruction record. ( )

c. A licensed pharmacist at the charitable clinic or center must document receipt of each donated drug on each manifest. ( )

d. In the event that the identifying patient information is not removed by the donating entity, the pharmacist at the charitable clinic or center must remove or redact that information. ( )

04. Storage of Donated Drugs. ( )

a. Drug storage must have proper environmental controls to assure the integrity of the drug in accordance with the drug manufacturer's recommendations and United States Pharmacopoeia standards. ( )

b. Donated drugs may be commingled with the charitable clinic or center's regular stock of drugs only if the packaging on the donated drugs has been labeled to show that the drugs were obtained through a donating entity. ( )

c. Donated drugs with packaging that has not been labeled to show that the drugs were obtained through a donating entity must be kept in an area that is separately designated from the charitable clinic or center's regular stock of drugs. ( )

d. The space in which drugs are stored must be locked at all times except during operating hours or other time when a licensed pharmacist or physician is physically present in the charitable clinic or center. ( )

05. Dispensing Donated Drugs to Medically Indigent Patients. ( )

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions must not be re-dispensed to indigent patients and must be destroyed. Documentation of such destruction must be maintained within a destruction record. ( )

b. A pharmacist or physician working at a charitable clinic or center who re-dispenses donated drugs to any patient must: ( )

i. Utilize a proper and appropriate container; ( )

ii. Place a label on the container that conforms to provisions of these rules; and ( )

iii. Initial the prescription label. ( )

c. The re-dispensed drug must be assigned the same expiration date as is on the original package. ( )

d. A charitable clinic or center must maintain dispensing records for each donated drug dispensed. ( )

e. Pharmacists or physicians dispensing donated drugs are required to provide patient counseling. ( )

06. Miscellaneous. ( )

a. A licensed pharmacist or physician must be on duty during all hours of operation of the charitable clinic or center. ( )

b. Legend drugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. ( )

c. Nothing in these rules precludes a charitable clinic or center from charging an indigent patient a dispensing fee. ( )

07. Record Keeping Requirements. ( )

a. Donating entities must maintain all manifests in a readily retrievable fashion for at least two (2) years. ( )

b. Charitable clinics or centers must maintain destruction records, dispensing records, and manifests in a readily retrievable fashion for at least two (2) years. ( )

381. -- 400. (RESERVED).

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0905

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rulemaking is necessary to allow pharmacists to provide up to a three (3)-month supply of legend drugs that are not controlled substances, when a prescription is written for a smaller supply but includes refills sufficient to equal the larger supply. The proposed rulemaking amends an existing rule to clarify that a pharmacist, filling a drug order for a legend drug that is not a controlled substance, may provide up to a three (3)-month supply when the practitioner has written a prescription for a smaller supply with refills in sufficient numbers to fill the larger supply.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking: NA

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0905

184. UNPROFESSIONAL CONDUCT.
The following acts or practices by a licensed pharmacist or a pharmacy owner declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: (7-1-93)

01. General. Manufacturing, compounding, selling, or dispensing or permitting to be manufactured, compounded, sold, or dispensed substandard drugs or preparations. (7-1-93)

02. Secret Formulas. Using secret formulas. (7-1-93)

03. Prescriber Incentives. Allowing a commission or rebate to be paid to a person writing, making, or otherwise ordering a prescription, or providing consultant services at no charge to receive prescription business. (7-1-93)

04. Prescription Order Noncompliance. Failing to strictly follow the instructions of the person writing, making, or ordering a prescription as to refills, contents, or label, or giving a copy of a prescription to any person without marking said prescription across the face: "Copy for Information Only. Not to Be Filled," except that a pharmacist, utilizing his best professional judgment, may provide up to a three-month supply of a legend drug that is not a controlled substance when the practitioner has written a drug order to be filled with a smaller supply but which includes refills in sufficient numbers to fill a three (3) month supply. ~~(7-1-93)~~( )

05. Errors or Omissions. Failing to confer with the person writing, making or ordering a prescription, if there is an error or omission therein which should be questioned. (7-1-93)

06. False or Deceptive Advertising. Advertising in a manner that is false, misleading or deceptive, which includes making material claims of professional superiority that cannot be substantiated. (7-1-93)

07. Addiction. Being addicted or habituated to the use of alcohol or controlled substances. (7-1-93)

08. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices, legally sold in pharmacies, that allows unqualified persons to circumvent laws pertaining to the legal sale of such articles. (7-1-93)

09. Fraudulent Practice. Performing, or in any way being a party to, any fraudulent or deceitful practice or transaction. (7-1-93)

10. Incompetency and Negligence. Performing duties as a pharmacist or pharmacy owner in an incompetent, unskilled, or negligent manner. (7-1-93)

11. Unprofessional Conduct. Exhibiting unprofessional conduct toward customers, employees, colleagues, inspectors or others. (7-1-93)

12. Insubordination. Failure to follow an order of the Board. (2-23-94)

13. Inappropriate Conduct. Any activity by a pharmacist that is inappropriate to the conduct of the profession of pharmacy. (2-23-94)

14. Disciplinary Actions in Other States. Conduct that results in a suspension, revocation or other disciplinary proceeding or action with respect to a pharmacy or pharmacist license that the Idaho licensee holds in another state. (7-1-98)

15. Reporting Theft, Loss, or Adulteration. Failure of any pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances or any adulteration of a prescription drug to the Board, even if the theft, loss, or adulteration was accounted for and the employee was disciplined by the employer. (4-6-05)

16. Cooperating in an Investigation. Failure of any licensee to cooperate with a disciplinary investigation. (4-6-05)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0906

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rulemaking is necessary to allow pharmacists to provide pharmaceutical care outside of a licensed pharmacy under certain conditions. The proposed rules set forth the conditions under which a licensed pharmacist may practice outside a licensed pharmacy. These conditions address access to records and information, provide for security and documentation, and mandate the maintenance of records to provide accountability and an audit trail.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0906

165. PHARMACEUTICAL CARE.
A licensed pharmacist's scope of pharmacy practice may include, but is not limited to, the provision of those acts or services necessary to provide pharmaceutical care as defined in these rules. (5-8-09)

01. Definitions. (7-1-99)

a. Collaborative pharmacy practice. Means that practice of pharmacy whereby one (1) or more pharmacists have jointly agreed to work in conjunction with one (1) or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner under certain specified conditions or limitations. (5-8-09)

b. Collaborative pharmacy practice agreement. Means a written and signed agreement between one (1) or more pharmacists and one (1) or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting drug therapy management services, as defined in these rules. (5-8-09)

c. Drug therapy management. Means a distinct service or group of services that optimize therapeutic outcomes for individual patients. Drug therapy management services are independent of, but can occur in conjunction with, the provision of a drug or a device. Drug therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient: (5-8-09)

i. Performing or obtaining necessary assessments of the patient's health status; (5-8-09)

ii. Formulating a drug treatment plan; (5-8-09)

iii. Selecting, initiating, modifying, or administering drug therapy; (5-8-09)

iv. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness; (5-8-09)

v. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (5-8-09)

vi. Documenting the care delivered and communicating essential information to the patient's other primary care providers; (5-8-09)

vii. Providing information, support services and resources designed to enhance patient adherence with his therapeutic regimens; (5-8-09)

viii. Coordinating and integrating drug therapy management services within the broader health care-management services being provided to the patient; and (5-8-09)

ix. Such other drug therapy management services as may be allowed by law. (5-8-09)

d. Health information. Means any information, whether oral or recorded in any form or medium, that: (5-8-09)

i. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (5-8-09)

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of healthcare to an individual. (5-8-09)

e. HIPAA. Means the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof. (5-8-09)

f. Individually identifiable health information. Means information that is a subset of health information, including demographic information collected from an individual and that: (5-8-09)

i. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (5-8-09)

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (5-8-09)

(1) Identifies the individual; or (5-8-09)

(2) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (5-8-09)

g. Other pharmaceutical patient care services. Means services that may include, but are not limited to, the following: (5-8-09)

i. Collaborative pharmacy practice. (5-8-09)

ii. Such other pharmaceutical patient care services as may be allowed by law. (5-8-09)

h. Pharmaceutical care. Means the provision by a pharmacist of drug therapy management services and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in these rules. (5-8-09)

i. Pharmacist's scope of practice pursuant to the collaborative practice agreement. Means those duties and limitations of duties placed upon one (1) or more pharmacists by the collaborative practitioner or practitioners, the Board, and applicable law and includes the limitations implied by the scope of practice of the collaborating practitioner or practitioners. (5-8-09)

j. Practitioner. Means, for purposes of Section 165, an individual currently licensed, registered, or otherwise authorized in Idaho to prescribe and administer drugs in the course of professional practice. (5-8-09)

k. Protected health information. Means individually identifiable health information that, except as provided in Subparagraph 165.01.k.iv. of these rules, is: (5-8-09)

i. Transmitted by electronic media; (5-8-09)

ii. Maintained in any medium described in the definition of electronic media at 45 CFR 162.103 (HIPAA privacy rules); and (5-8-09)

iii. Transmitted or maintained in any other form or medium. (5-8-09)

iv. Protected health information excludes individually identifiable health information in: (5-8-09)

(1) Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1231(g)); (5-8-09)

(2) Records described at 20 U.S.C. Section 1231 (g)(4)(B)(iv); and (5-8-09)

(3) Employment records held by a licensee in its role as an employer. (5-8-09)

02. Collaborative Pharmacy Practice. Collaborative pharmacy practice is subject to the following requirements: (5-8-09)

a. Collaborative pharmacy practice agreement. A pharmacist planning to engage in collaborative pharmacy practice shall have on file at his place of practice the written collaborative pharmacy practice agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the collaborative pharmacy practice agreement including the agreement itself, shall be made available to the Board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management services approved by the practitioner and as defined by these rules. The collaboration that the practitioner agrees to conduct with the pharmacist must be within the scope of the practitioner's current practice. Patients or caregivers shall be advised of such agreement. (5-8-09)

b. Contents. The collaborative pharmacy practice agreement shall include: (5-8-09)

i. Identification of the practitioner and pharmacist who are parties to the agreement; (5-8-09)

ii. The types of drug therapy management decisions that the pharmacist is allowed to make; (5-8-09)

iii. A method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary; (5-8-09)

iv. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever he deems it necessary or appropriate; (5-8-09)

v. A provision that allows either party to cancel the agreement by written notification; (5-8-09)

vi. An effective date; and (5-8-09)

vii. Signatures of each collaborating pharmacist and practitioner who are parties to the agreement as well as dates of signing. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (5-8-09)

c. Initiation of the collaborative pharmacy practice agreement. The collaborative pharmacy practice agreement must be coupled with a medical order from the practitioner to initiate allowed activities for any particular patient. (5-8-09)

d. Documentation of pharmacist activities. Documentation of allowed activities must be kept as part of the patient's permanent record and must be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information. (5-8-09)

e. Review. At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year. (5-8-09)

03. Independent Practice. A licensed pharmacist may provide pharmaceutical care outside of a licensed pharmacy if all of the following conditions are met: ( )

a. The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of pharmaceutical care and appropriately reviews such information before performing any such functions; ( )

b. Access to the information described in Paragraph 165.03.a. of these rules is secure from unauthorized access and use, and all access by pharmacists is documented; and ( )

c. A pharmacist providing pharmaceutical care outside of the premises of a licensed pharmacy shall

maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall: ( )

i. Provide accountability and an audit trail; ( )

ii. Be provided to the Board upon request; and ( )

iii. Be preserved for a period of at least two (2) years from the date relied upon or consulted for the purposes of performing any such function. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0907

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rulemaking is necessary to reflect changes made by the 2009 Idaho Legislature to the Wholesale Drug Distribution Act. The proposed rule adds repackagers who are authorized distributors of record for FDA registered manufacturers to the definition of normal distribution channel.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking and the need to reflect changes made in current law.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0907

321. DEFINITIONS.

01. Authentication. To affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred. (4-2-08)

02. Authorized Distributor of Record. A wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following: (4-2-08)

a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (4-2-08)

b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis. (4-2-08)

03. Chain Pharmacy Warehouse. A physical location for prescription drugs that acts as a central warehouse and performs intra-company sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control. (4-2-08)

04. Co-Licensed Partner or Product. An instance where two (2) or more parties have the right to engage in the manufacturing or marketing, or both, of a prescription drug consistent with the federal Food and Drug Administration's implementation of the Prescription Drug Marketing Act. (4-2-08)

05. Components. Articles intended for use as a component of any articles specified in Subsections 321.01, 321.02, or 321.03 of these rules. (4-2-08)

06. Drop Shipment. The sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug. The wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor. (4-2-08)

07. Drug. Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or their supplement. (7-1-93)

08. Facility. Facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale. (4-2-08)

09. Manufacturer. A person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices consistent with the federal Food and Drug Administration definition of "manufacturer" under its regulations and guidance implementing the Prescription Drug Marketing Act. (4-2-08)

10. Manufacturer's Exclusive Distributor. A person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be

considered part of the normal distribution channel. (4-2-08)

11. Normal Distribution Channel. A chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its co-licensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States Food and Drug Administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States Food and Drug Administration, either directly or by drop shipment to:
~~(4-2-08)~~( )

a. A pharmacy to a patient; (4-2-08)

b. A designated person authorized by law to dispense or administer such drug to a patient; (4-2-08)

c. A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; (4-2-08)

d. A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or (4-2-08)

e. A chain pharmacy warehouse to the chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient. (4-2-08)

12. Pedigree. A document or electronic file containing information that records each wholesale distribution of a prescription drug. (4-2-08)

13. Prescription Drug. Any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by prescription, including finished dosage forms and bulk substances, subject to Section 503(b) of the federal Food, Drug and Cosmetic Act. (4-2-08)

14. Repackage. Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding any repackaging completed by the pharmacist responsible for the purpose of dispensing the drug to the patient. (4-2-08)

15. Repackager. A person who repackages. (4-2-08)

16. Sample. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (4-2-08)

17. Third Party Logistics Provider. A person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but who does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third party logistics provider must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be considered part of the normal distribution channel. (4-2-08)

18. Wholesale Distribution. Distribution of prescription drugs to persons other than a consumer or patient, but excluding the following: (4-2-08)

a. Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between co-licensees of a co-licensed product. (4-2-08)

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or the offer to sell,

purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons. (4-2-08)

c. The distribution of prescription drug samples by manufacturers' representatives. (4-2-08)

d. Drug returns when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23. (4-2-08)

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use. (4-2-08)

f. The sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription. (4-2-08)

g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets. (4-2-08)

h. The sale, purchase, distribution, trade, or transfer of a prescription drug from one (1) authorized distributor of record to one (1) additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had, to date, been exclusively in the normal distribution channel. (4-2-08)

i. The delivery of, or the offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs if the common carrier does not store, warehouse, or take legal ownership of the prescription drug. (4-2-08)

j. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or third party returns processor, including a reverse distributor. (4-2-08)

19. Wholesale Distributor. A person engaged in wholesale distribution of drugs including, but not limited to: manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturer's and distributor's warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel, a wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record. (4-2-08)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0908

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rulemaking is necessary to clarify that a pharmacy may transfer a prescription to another pharmacy without first having to fill it. The proposed rule will permit a pharmacist to transfer a prescription to another pharmacy to be filled or refilled. The rule will also clarify the recordkeeping responsibility of the receiving pharmacy.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

No fees or charges are being imposed or increased through this rulemaking.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0908

160. PRESCRIPTION TRANSFER.
A pharmacist may transfer prescription order information for the purpose of filling or refilling a prescription only if the information is communicated orally directly from pharmacist to pharmacist. Such oral information can be communicated by a student pharmacist, under the direct supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. In the alternative, the transferring pharmacist may transfer the prescription order information by facsimile transmission to the receiving pharmacist. In the case of a facsimile transmission, the transmission shall be signed by the transferring pharmacist. ~~(5-8-09)~~( )

01. Transferring Prescriptions for Controlled Substances. A prescription for a controlled substance may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer. (7-1-93)

a. In addition to the information required in Subsection 160.02 the pharmacist transferring the prescription shall record on the back of the original order the DEA number and address of the pharmacy to which the transfer was made. (7-1-93)

b. The receiving pharmacist must record the DEA number and address of the pharmacy transferring the order. (7-1-93)

02. Documenting the Transfer of a Prescription. The pharmacist who transfers the prescription shall: (5-8-09)

a. Invalidate the original prescription by writing the word "void" across the face of the form; and (7-1-93)

b. On the back of the form, record the following information: his name; name of the receiving individual; name of the receiving pharmacy; date of the transfer, and the number of authorized refills available. (7-1-93)

03. Documenting the Receipt of a Transferred Prescription. The pharmacist who receives the transferred prescription shall: (5-8-09)

a. Reduce the transferred information to writing including all information required by law or rule and a notation that the prescription is a "transfer"; and (7-1-93)

b. On ~~the back of~~ the form, record the following information: his name; the name of the transferring individual; the name of the transferring pharmacy; the date of the original dispensing and transfer, the number of refills authorized, the number of valid refills remaining, the date of the last refill, and the serial number of the prescription transferred. ~~(7-1-93)~~( )

04. Documenting Prescription Transfers by Computer. Transferring pharmacies that utilize a computer prescription database that contains all of the prescription information required by law or rule may enter the information required under Section 160 of these rules into the pharmacy's prescription database (including de-activation of the transferred prescription in the database of the transferring pharmacy) in lieu of entry of the required information on the original written prescription. ~~*The receiving pharmacy must generate a hard copy to be treated as a new prescription, and the hard copy shall also contain all of the information required under Section 160 of these rules.*~~ ~~(3-30-01)~~( )

05. Documenting Receipt of Prescription Transfers by Computer. A receiving pharmacy that utilizes a computer prescription database that contains all of the prescription information required by law or rule must generate a hard copy to be treated as a new prescription; however, the receiving pharmacy may enter the information required under Section 160 of these rules into the pharmacy's prescription database in lieu of writing the information

on the hard copy of the new prescription. ( )

05~~5~~6. Transferring Prescription Refills. Prescriptions for non-controlled drugs may be transferred more than one (1) time as long as there are refills remaining and all of the provisions of these rules are followed. (7-1-93)

06~~7~~7. Transferring Prescription Between Pharmacies Using Common Electronic Prescription Files. (7-1-98)

a. For prescriptions written for drugs other than controlled substances two (2) or more pharmacies may establish and use a common electronic prescription file to maintain required dispensing information. Pharmacies using the common file are not required to transfer prescriptions or information for dispensing purposes between or among other pharmacies using in the same common electronic prescription file. (7-1-98)

b. For controlled substances pharmacies using a common electronic prescription must satisfy all documentation requirements of a manual prescription transfer. (7-1-98)

c. All common electronic prescription files must contain complete and accurate records of each prescription and refill dispensed. Hard copies must be generated and treated as new prescriptions by the receiving pharmacies. (7-1-98)