



**MAINE DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION**  
**Office of Professional and Occupational Regulation**

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Janet T. Mills  
Governor

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To: Joe Bruno, Board President and Members of the Board

From: Jeri Betts, Administrator 

RE: Major Substantive Rulemaking – Chapter 12 Licensure of Manufacturers and Wholesalers

Date: April 23, 2020

**Background:**

2017 Public Law, Chapter 267, 32 M.R.S. §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners” directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

On June 6, 2019, the Maine Board of Pharmacy voted to provisionally adopt these rules, which pursuant to 32 MRS § 13759 are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

On February 12, 2020, the Committee on Health Coverage, Insurance and Financial Services reported out LD 1872 (Emergency Preamble, Resolve, Regarding Legislative Review of Portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a Major Substantive Rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy) Ought to Pass with no changes to the provisionally adopted rule and finally passed by the Maine Legislature on February 25, 2020.

On March 9, 2020, Governor Mills signed 2020 Public Law Chapter 115 (LD 1872) Emergency Preamble, Resolve, Regarding Legislative Review of Portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a Major Substantive Rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy.

In order for the Final Adoption and submission of this rule to occur, the Board must vote to accept the rules for Final Adoption (MAPA 1 Adoption attached).

Attached are the documents that were prepared during the provisional adoption stage. Because the Legislature accepted fully the provisionally adopted rule, with no changes to the provisionally adopted rule, none of the documents prepared at the time of the provisional adoption stage is required and stand as is.

**Attached:**

Chapter 12 Rule w/Strikeouts and Underlines  
Fact Sheet  
Basis Statement and Response to Comments  
LR-2019-9 (SOS) 07152019  
PLC 115 (LD 1872)

# Rule-Making Fact Sheet

(5 MRSA §8057-A)

AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy.

CHAPTER NUMBER AND RULE TITLE: Chapter 12 “Licensure of Manufacturers and Wholesalers”.

STATUTORY AUTHORITY: 32 M.R.S. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

DATE, TIME AND PLACE OF PUBLIC HEARING: May 8, 2019, 8:00 a.m., 76 Northern Avenue, Gardiner, Maine 04333, Central Conference Room.

COMMENT DEADLINE: May 19, 2019 by 5:00 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: 2017 Public Law, Chapter 267, 32 M.R.S. §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners” directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? \_\_\_YES XNO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [see §8057-A(1)(B) &(D)]

This chapter establishes procedures and standards for licensure, reporting requirements and guidelines specific to pharmacy wholesalers and manufactures.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]

Title 42 Code of Federal Regulations; Sunshine Act; legislation enacted in other states; staff input; definitions in current Maine Board of Pharmacy rules; Regulations from the Maine Board of Medicine; and American Code of Medical Ethics Opinion 9.6.2.

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)] None.

***FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:***

ECONOMIC IMPACT, IF QUANTIFIABLE IN MONETARY TERMS:

[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

*Note: If necessary, additional pages may be used.*

06/06/2019

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 BOARD OF PHARMACY

Chapter 12 LICENSURE OF MANUFACTURERS AND WHOLESALERS

PROVISIONALLY ADOPTED JUNE 6, 2019

**BASIS STATEMENT AND SUMMARY OF COMMENTS & RESPONSES**

***Basis Statement***

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This Rule is proposed in response to Public Law 2017, Chapter 267, 32 M.R.S. § 13759 “An Act to Prohibit Certain Gifts to Health Care Practitioners”, directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. The proposed rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

The initial Notice of Proposed Rulemaking was published on April 17, 2019 with a public hearing of May 8, 2019 and written comment deadline of May 19, 2019 at 5:00 p.m.

***Response to Comments***

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**List of Commenters:**

SUBMITTING WRITTEN COMMENTS:

- Shirlyn Adkins, 2621 Rochester, MN, (*Executive Director, of a nonprofit education physicians on neuromuscular diseases*)
- Kelsey Almy, Grand Junction, CO (*self-Almy*)
- Nicholas Argento, Columbia, MD (*self-Argento*)
- Betti Bandura, Thorofare, NJ (*self-Bandura*)
- Faith Bantivoglio, Thorofare, NJ (*self-Bantivoglio*)
- Robert Batte, Oldsmar, FL (*self-Batte*)
- Leanne Berger, Encinitas, CA (*self-Berger*)
- Christopher Bolwell, Alpharetta, GA (*self-Bolwell*)
- Michelle Bonnarens, Fort Wayne, TN (*self-Bonnarens*)
- Sara Brykalski, Chicago, IL (*self-Brykalski*)
- Donald Budenz, Chapel Hill, NC (*self-Budenz*)
- Courtney Burbridge, GA (*self-Burbridge*)
- John Burr, Bloomington, IL (*self-Bloomington*)
- Melissa Carter, Prairieville, LA (*self-Carter*)
- Karen Catino, Chicago, IL (*self-Catino*)
- Hope Carr, Stamford, CT (*self-Carr*)
- Michael Chang, Portland, OR (*self-Chang*)
- Ruth Cohen, Old Greenwich, CT (*self-Cohen*)
- Katlyn Cooper, Chicago, IL (*self-Cooper*)
- Kimberly Corbin, New York, NY (*self-Corbin*)
- Tracey Cross, Sheboygan Falls, CT (*self-Cross*)
- Tara Curran, Thorofare, NJ (*self-Curran*)
- Mindi Daiga, Mount Prospect, IL (*self-Daiga*)
- Jerri Davis, San Francisco, CA (*self-Davis*)
- Richard de Ramon, Mechanicsburg, PA, self (*de Ramon*)

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- Carol Derman, Wilmington, DE, self (*Derman*)
- Kimi Dolan, Thorofare, NJ, self (*Dolan*)
- Melodye Farrar, Saint Petersburg, FL, self (*Farrar*)
- Michelle Forcier, Chicago, IL, self (*Forcier*)
- Karen Fountain, Escondido, CA, self (*Fountain*)
- Michael Fredericks, Halifax, VA, self (*Fredericks*)
- Arielle Garbarino, Thorofare, NJ, self (*Garbarino*)
- Casey Garrison, Catonsville, MD, self (*Garrison*)
- Bina GeorgeFiguerola, Weston, FL, self (*GeorgeFiguerola*)
- Terry Glauser, Norwood, MA, self-medical professional (*Norwood*)
- Jaimee Gold, Nazareth, PA, self (*self-Gold*)
- Alan Goldenhar, Fryeburg, ME (*Goldenhar*)
- Genevieve Griffith, Thorofare, NJ, self, CME provider (*Griffith*)
- Amy Groves, Mobile, AL, self (*Groves*)
- Judy Hyle, CHCP, Montclair, CA, self (*Hyle*)
- Keith Johnson, Trenton, NJ, self (*Johnson*)
- Jody Johnston-Mohr, Rock Island, IL, self (*Johnston-Mohr*)
- Lauri Jorgensen, Holmdel, NJ, self (*Jorgensen*)
- John Juchniewicz, MCIS, CHCP, Jackson, NJ, self (*Juchniewicz*)
- Nusinyo Kakrada, Annapolis, MD, self, medical professional (*Kakrada*)
- Ade Kamson, Inglewood, CA, self (*Kamson*)
- Lisa Keckich, Oak Park, IL, self (*Keckich*)
- Richard Keenan, West Chester, PA, self (*Keenan*)
- Sophia Kelley, Powder Springs, GA, (*Kelly, Clinical Care Options, LLC*)
- Joseph Kim, Newton, PA, self (*Kim*)
- Melissa Klingler, New York, NY, self (*Klingler*)
- Anne Kramer, Johns Creek, GA, self (*Kramer*)
- Christopher Kriz, MHA, CHCP, Hobe Sound, FL, self (*Kriz*)
- Shauna Labo, Mobile, AL, self (*Labo*)
- Sandra Latham, Thorofare, NJ, self (*Latham*)
- Megan Lewis, Thorofare, NJ, self (*Lewis*)
- Robert Lowney, West Hartford, CT, self (*Lowney*)
- Barbara Lyon, Fairfield, CT, self (*Lyon*)
- Wendy Macias, San Antonio, TX, self (*Macias*)
- Celina Makowski, Saint Augustine, FL, self (*Makowski*)
- Christy Marsh, Woodbury, NJ, self (*Marsh*)
- Niles McCall, Los Lunas, NM, self (*McCall*)
- Katherine McCue, Chicago, IL, self (*McCue*)
- Kelly McCulloch, Oldsmar, FL, self (*McCulloch*)
- Tim McGuire, Carmel, IN, self (*McGuire*)
- William Mitch, Houston, TX, self (*Mitch*)
- Tim Mitchell, Redding, CT, self (*Mitchell*)
- Lisa Noble, South Plainfield, NJ, self (*Noble*)
- Katie Oakes, Clackamas, OR, self, CME planner (*CME planner-Oakes*)
- Justine Oldt, Thorofare, NJ, self (*Oldt*)
- Lindsey Owen, Thorofare, NJ, self (*Owen*)
- Fernando Pagan, Washington, DC, self (*Pagan*)
- Michelle Palumbo, Poughkeepsie, NY, self (*Palumbo*)
- Joe Panarelli, Scarsdale, NY, self (*Panarelli*)

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- Kathy Pitura, East Hartford, CT, self (*Pitura*)
  - Charles Pollack, Saint Davids, PA, self (*Clinician-scientist in academic practice-Pollack*)
  - Brittany Puster, Chicago, IL, self (*Puster*)
  - Tony Realini, Morgantown, WV, self (*International expert-Realini*)
  - Kristin Riday, Thorofare, NJ, self (*Riday*)
  - Nicolle Rochino, Edison, NJ, self (*Rochino*)
  - BJ Rose, Mantua, NJ, self (*Rose*)
  - Blair St. Armand, Elkridge, MD, self (*St. Armand*)
  - Lu Salazar, Washington, DC, self (*Salazar*)
  - Amy Schall, Saint Paul Park, MN, self (*Schall*)
  - Erin Schwarz, Foothill Ranch, CA, self (*Schwarz*)
  - Daniel Siegel, Saint James, NY, self (*Siegel*)
  - Rishi Singh, Shaker Heights, OH, self, Physican and educator (*Singh*)
  - Ashley Sipes, Shreveport, LA, self (*Sipes*)
  - Kimberly Sponza, Norwalk, CT, self (*Sponza*)
  - Heather Steelman, Denver, CO, self (*Steelman*)
  - Angela Still, Thorofare, NJ, self (*Still*)
  - Debi Susalka, Collegeville, PA, self (*Susalka*)
  - Paula Talbott, Columbia, MD, self (*Talbott, Columbia, MD*)
  - Paula Talbott, Huntingtown, MD, self (*Talbott, Huntingtown, MD*)
  - Heather Tarbox, Old Lyme, CT, self (*Tarbox*)
  - Renee Thomas, Camden, SC, self (*Thomas*)
  - Darla Thompson, Thorofare, NJ, self (*Thompson*)
  - Cynthia Tonallyay, RD, MBA, CCMEP, Redding, CT, self (*Tonallyay, Cynthia*)
  - Steve Tornallyay, Berkeley, CA, self (*Tornallyay, Steve*)
  - Wendy Turell, Montclair, NJ, self, CME professional (*Turell*)
  - Paul Tyndall, Wilmington, NC, self (*Tyndall*)
  - Meredith Vaccaro, Catonsville, MD, self (*Vaccaro*)
  - Mira Valkova, McLean, VA, self, Medical professional (*Valkova*)
  - Teri Valls, Miami, FL, self (*Valls*)
  - Jerrold Vitek, Roseville, MN, self (*Vitek*)
  - Kathy Whyte, Laurel, MD, self, Medical professional (*Whyte*)
  - Paula Williams, Malvern, PA, self (*Williams*)
  - Chad Williamson, Columbia, MD, self (*Williamson*)
  - Charles Willis, Rancho Mirage, CA, self, Hospital-based educational activities (*Willis*)
  - Andrew Antrobus, Sr. Director, Pfizer Government Relations, Pfizer, Inc., New York, NY, on behalf of Pfizer, Inc. (*Antrobus - Pfizer, Inc.*)
  - Brian Bohnenkamp, Nikki Reeves, Seth H. Lundy, King & Spalding LLP, Washington, DC, on behalf of the Ad Hoc Sunshine and State Law Compliance Group (*Ad-Hoc Bohnenkamp*)
  - Adrienne Brown, Windham, ME, self (*Brown*)
  - Terry Chang, MD, JD, Washington DC, and Chris L. White, COO and General Counsel, on behalf of Advanced Medical Technology Assoc. (AdvaMed) (*AdvaMed Chang*)
  - David C. Tilton, Portland ME, self (*Tilton*)
  - Howard Fienberg, VP Advocacy, Washington DC, on behalf of The Insights Association (*Insights-Fienberg*)
  - Jack Geisser, Director, Healthcare Policy, Medicaid, and State Initiatives, Washington DC, (on behalf of Biotechnology Innovation Organization (BIO), (*BIO-Geisser*))
  - Andrew Rosenberg, Sr. Advisor, CME Coalition, Washington DC, on behalf of CME Coalition *CME Coalition-Rosenberg*)
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**Summary of Comments and Board Responses:**

1. Most comments received opposed the \$250.00 honoraria limit and request that the Board consider exempting accredited continuing medical education (CME) activities. Most of the individual comments were written in template format with the same or similar message as follows:

*“I am writing to urge the Maine Board of Pharmacy to exempt accredited continuing medical education (CME) activities from its proposed limit of \$250 on certain payments to physicians. CME is a critical for the ongoing education of Maine doctors, and honoraria in exchange for physicians’ teaching their peers helps offset the time and financial costs of supporting CME programs.*

*I appreciate the goal of eliminating potential conflicts of interest by restricting industry gifts to physicians. However, the language proposed is too restrictive. Limiting the amount to \$250 per year is too low. This will have a chilling effect on professional training for Maine medical professionals by other Maine medical professionals. The nature of medicine involves constant advancement, testing, and application, often involving landmark breakthroughs. Given the sheer volume of new scientific data and changes in medicine, it is important to encourage – rather than hinder – physician participation in CME.*

*Patients count on doctors to be up to date with the latest medical breakthroughs, and CME providers’ doctors with that knowledge. For that reason, I respectfully request that you exempt programs approved by the ACCME and other accreditors from the \$250 limit and allow physicians to be fairly compensated for sharing their time and knowledge with their peers.”*

Some commenters added their personal unique comments, following is a brief summation:

- A. *“Honoraria is a vital aspect of obtaining important speakers and experts in the field of delivering appropriate education. Speakers should be compensated as putting together talks that met all CME criteria takes time and expertise to conduct. If Maine’s proposal passes...what other states will follow suite. ACCME has already added 13 new criteria which makes obtaining accreditation more rigorous. Adding this ban could potentially reduce the quality of CME education, not improve it. (Almy)*
- B. *“I find this proposal to be very disturbing and exceedingly shortsighted. Sharing knowledge and clinical experience is critical in improving patient care. To effectively share ideas, treatment approaches and updates on newer medications/devices, we need physicians with expertise in these areas to be able to serve as Subject Matter Experts and to do this in widely distributed geographic areas...A \$250 limit to honorarium provided to someone that is going to have to take a minimum of ½ day out of his/her clinical practice to do a presentation is going to stifle educational activities, decrease communication between practitioners from different regions and ultimately cause a decline in care provided to patients.” (Batte)*
- C. *“CME activities are not provided by industry to physicians, CME activities are provided by accredited organization, a small portion of which may receive education grants from industry...If the reason [for \$250 limit] is because of the perceived bias which they consider to be associated with activities supported by educational grants from the industry, then this just demonstrates the lack of knowledge and understanding of the rules and guidelines of the accrediting bodies as well as contrary to the vast majority of published data on this matter.” (Bolwell)*
- D. *“I currently work for a professional pharmacy society in the field of CME and it is important that we fairly compensate our medical professionals for their participation in our scientifically balanced, unbiased education that we provide. The proposed limit would severely impair our efforts to find qualified physician speakers for important programming that prepares other health care professionals to provide the best possible, safe, and effective care.” (Bonnarens)*
- E. *“Physician time is not free. Further, academic physicians, who provide the bulk of CME services, are reimbursed substantially less than private practice providers, putting a higher premium on their discretionary time. To get Faculty to spend time on nights and weekends, one must incentivize that work. Otherwise, either the quality will plummet or there simply won’t be anyone around to provide the CME.” (Chang)*
- F. *“To limit the compensation given to a physician teacher will have the effect of forcing physician teachers to refrain from participating in educational activities because it will, in the longer run, end up costing them*

money. More importantly, physicians in need of education on the latest developments in medicine will be deprived of training from the thought leaders who can provide it.” (Corbin)

- G. “Patients count on doctors to be up to date with the latest medical breakthroughs, and CME provides doctors with that knowledge – there is never a direct payment made.” (Daiga)
  - H. “Accredited education is highly regulated and the process of producing this education ensures that there is a firewall between any commercial/pharma support and the ultimate education provided to learners...We believe that \$250 is not enough in many cases to compensate the faculty physician experts that we ask to pull together the latest evidence-based curriculum.” (Davis)
  - I. “If the Maine bill is approved, personalized medical therapies that save lives and the future of medicine will be severely compensated.” (Derman)
  - J. “Please bear in mind that accredited CME honoraria are never directly paid by a pharmaceutical company to a speaker. All honoraria are paid by the accredited provider, so the “cash” is not coming from the manufacturer, it is coming from the CME provider...as an accredited provider of CME at a national level, I can say with 100% certainty that no one would give even one 60-minute presentation ... for \$250, let alone an annual maximum of \$250. To be well prepared we require speakers to review/edit the presentation at home, to be onsite 1 day prior to speaking for a final review/run through, and then to stick around after their talk for at least ½ day to answer questions....12 hours of work time, plus the content review time at home, and all for \$250 per year?” (Fountain)
  - K. “...\$250 is simply not enough compensation for what we are asking [presenters] to do – leave their office, in most cases for several days, and leave their families – for a 2-hour presentation. The rest of us are compensated by our employers for this time away – our faculty are not. This proposal is completely ludicrous.” (Groves)
  - L. “It is in Maine’s best interest to not stifle but to support accredited CME programs by allowing them to utilize respected faculty...as currently drafted, we believe this proposed rule does not meet that need by failing to allow for CME providers to reasonably compensate Maine faculty for work involved in delivering accredited educational programs. In short, the proposed rule disincentivizes Maine faculty members from participating in CME activities. Eliminating the proposed rule’s strict limitation on the provision of honoraria to faculty members participating in accredited CME activities will allow physicians to continue to participate in CME without the risk of conflict-of-interest Maine rightly seeks to curtail.” (CME Coalition-Rosenberg)
  - M. “I am disabled with Multiple Sclerosis, anxiety and depression...I rely on the free programs sponsored by the drug companies for straight forward educational and social support...Don’t limit doctor educational consulting, clinical research or educational conferences and other opportunities for patients and doctors in Maine to educate themselves...” (Brown)
  - N. Mr. Tilton states that he and his wife attend patient educational programs about various MS drugs in support of his wife who has MS and feels that the \$250 honoraria cap for doctors is not realistic to cover the presenter’s costs and expenses. (Tilton)
2. Brian Bohnenkamp, Nikki Reeves, Seth H. Lundy, King & Spalding LLP, Washington, DC, on behalf of the Ad Hoc Sunshine and State Law Compliance Group (*Ad-Hoc Bohnenkamp*)

Andrew Antrobus, Sr. Director, Pfizer Government Relations, Pfizer, Inc., New York, NY, on behalf of Pfizer, Inc. (*Antrobus - Pfizer, Inc.*) “We support the recommendations submitted by the Biotechnology Innovation Organization (“BIO”) and the Ad Hoc Sunshine and State Law Compliance Group.”

A. WRITTEN COMMENT: REASONABLE HONORARIA, following is a brief summation.

“To help alleviate an unnecessary chilling of Maine practitioners’ participation in such third-party educational events and programs that are sponsored by manufacturers and wholesalers, the Ad Hoc Group requests that the Board make one of the following revisions to the proposed definition of “reasonable honoraria”:

“Option 1: Remove any express dollar limitation on practitioners’ receipt of honoraria.

Option 2: If the Board is not amendable to removing a specific dollar limitation, then the Ad Hoc Group requests that the Board clarify that the dollar limitation does not apply to professional or educational conferences sponsored by a manufacturer or wholesaler where the manufacturer or wholesaler does not select or influence the selection of which practitioners are speakers, as follows:"

*(Add to section 7(2))* The annual dollar limit shall not apply to professional or educational conferences sponsored by a manufacturer or wholesaler where the manufacturer or wholesaler does not select or influence the selection of which practitioners are speakers.”

**B. WRITTEN COMMENT: MODEST MEALS AND REFRESHMENTS**, following is a brief summation.

“To help avoid confusion and ensure consistency with the statute, the Ad Hoc Group respectfully requests that the Board make the following minor revision to the proposed definition to help avoid potential confusion”:

*Suggest amending section 7(1)* For purposes of 32 M.R.S. §13759(2)(A)(3), “modest meals and refreshments” means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quality typically provided for ~~conference~~ attendees at the venue where the meeting or presentation occurs.

3. Jack Geisser, Director, Healthcare Policy, Medicaid, and State Initiatives, Washington DC, (on behalf of Biotechnology Innovation Organization (BIO), *(BIO-Geisser)*)

**A. WRITTEN COMMENT: MODEST MEALS AND REFRESHMENTS**, following is a brief summation.

Under the proposed definition of modest meals and refreshments, there would be no basis to determine what is a typical meal in that particular venue, while being “a venue and manner conducive to information communication,” it is not a “conference” venue. The Board should consider the Commonwealth of Massachusetts definition, which defines, “modest meals and refreshments” as food and/or drinks provided by or paid for by a pharmaceutical manufacturer representative...that as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.

**B. WRITTEN COMMENT: HONORARIA**, following is a brief summation.

“BIO believes a better alternative to the arbitrary \$250 cap on honoraria, would be to impose a “fair market value” (FMV) threshold for honoraria instead. This would ensure that the state can attract top professionals and maintain high levels of patient care in the State of Maine. Furthermore, the Board must make it clear that the cap would not apply to out-of-state practitioners.”

**C. WRITTEN COMMENT: BONA FIDE SERVICE ARRANGEMENTS**, following is a brief summation.

“We are concerned that the statute, together with the regulations as drafted, does not explicitly exempt research. Nevertheless, we interpret the statute as to not apply to bona fide service arrangements between manufacturers and licensed practitioners/prescribers in Maine. These types of arrangements include but are not limited to research or clinical trials, as well as participation in scientific advisory boards. They are contractual arrangements that provide compensation based upon fair market value (FMV) for services rendered. These payments are not “gifts” as intended by the statute.”

4. Terry Chang, MD, JD, Washington DC, on behalf of Advanced Medical Technology Assoc. (AdvaMed) *(AdvaMed Chang)*



A. WRITTEN COMMENT: REASONABLE HONORARIA, following is a brief summation.

Amend as follows: For purposes of 32 M.R.S. §13759(2)(C), “reasonable honoraria” means cash and/or gift given to a practitioner in return for the practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of \$250 in retail value.

5. Howard Fienberg, VP Advocacy, Washington DC, on behalf of The Insights Association (*Insights-Fienberg*)

A. WRITTEN COMMENT: MARKETING RESEARCH STUDIES, following is a brief summation.

“[The] 2017 law has inadvertently banned respondent incentives for practitioners who participate in pharmaceutical marketing research studies, even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not aware of which practitioners participated. That is because pharmaceutical manufacturers’ compliance departments take the most conservative reading of such laws: if marketing research incentives are not explicitly exempted or excluded, those compliance departments will assume they are prohibited as “gifts.” Such has been the case across the industry since Maine passed this law two years ago.”

“Except for two states (Vermont and Maine), all permit such research and have little to no restrictions on marketing research incentive payments to the practitioners.”

This commenter suggests adding the following to the proposed rule:

For purposes of 32 M.R.S. § 13759, a “gift” does not include a payment to a practitioner for participation in bona fide marketing research conducted by a third party, if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating practitioner.

“Bona fide marketing research” means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant’s attitudes or behavior.

Or, “the simpler approach of clarifying that independent third-party marketing research companies are not “agents” of a manufacturer.”

For purposes of 32 M.R.S. § 13759(1), to the extent that a marketing research company does not engage in detailing, promotional activities, or other marketing of prescription drugs or biologics, such company, by definition, is not considered a manufacturer’s agent.

6. Amon Purinton, on behalf of Northern Light Health [Maine] (*Northern Light Health-Purinton*)

*Public hearing testimony: The scope of the rule applies generally to prohibit gifts to “practitioners,” which as defined in law is defined to reference prescribers. The proposed rule as written could be construed to include pharmacists. Mr. Purinton also raised question on what “honoraria” is meant for purposes of this proposed rule, which does not reflect the Board’s discussion at a prior meeting where the Board agreed that honoraria does not include the speaker’s fee for his or her presentation, but rather a token or gift bag above and beyond the speaker’s fee.*

BOARD'S RESPONSE TO COMMENTS

The Board appreciates all comments received. The following is the Board's response to all comments.

1. BOARD'S RESPONSE TO COMMENTS ON MODEST MEALS AND REFRESHMENTS

The Board agrees with commenters on the need for greater clarification on what the Board considers "minimal value" in relation to modest meals and refreshments and will amend the rule to clarify that "minimal value" means the cost of which is similar to that which a practitioner would pay when dining at his or her own expense as judged by local standards where the event is held.

The Board agrees to removing the word "conference" in Section 7, (1) for consistency with 32 M.R.S. §13759, Section 2(A)(3).

2. BOARD'S RESPONSE TO COMMENTS ON REASONABLE HONORARIA

The Board does not agree with comments to remove any express dollar limitation or to leave the honoraria to fair market value. The Board agrees that the \$250.00 may not be sufficient and agrees to place the honoraria cap at \$500.00. The Board agrees that the honoraria is a gift or gratuity in recognition of the practitioner's presentation and does not include fee for service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred.

The Board agrees that if a manufacturer or wholesaler sponsors a conference or meeting event with a dollar donation, and the manufacturer or the wholesaler does not and is not a participant in the selection of the practitioner chosen for the speaking engagement, nor does it influence or pay the practitioner directly, the honoraria limitation does not apply to such professional or educational meeting or presentation events.

The Board agrees on the need to clarify that "practitioner" does not include pharmacists. The term "practitioner" is defined under 32 M.R.S. §13702-A, Section 29 as, "...an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice." In addition, the Board agrees that this rule applies to Maine licensed practitioners and does not apply to practitioners licensed outside Maine.

3. BOARD'S RESPONSE TO COMMENTS ON BONA FIDE MARKETING RESEARCH

Commenters expressed concern that,

"[The] 2017 law has inadvertently banned respondent incentives for practitioners who participate in pharmaceutical marketing research studies, even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not aware of which practitioners participated."

"We are concerned that the statute, together with the regulations as drafted, does not explicitly exempt research. Nevertheless, we interpret the statute as to not apply to bona fide service arrangements between manufacturers and licensed practitioners/prescribers in Maine."

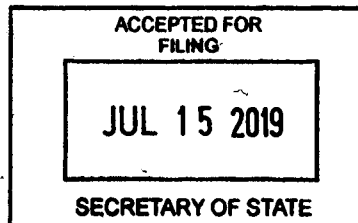
- BOARD'S RESPONSE: The Board understands the spirit of these comment. Pursuant to 32 M.R.S. §13759, the Maine Legislature directs the Board to define by rule "modest meals and refreshments" and "giving reasonable honoraria." Legislature. The Board does not believe the law prohibits payment to a practitioner for services rendered and would not be a matter subject to Board action. Addressing or proposing something other than a gift is not within the purview of the Board and a matter for the commenter to address directly with the Maine Legislature.

Rule-Making Cover Sheet

LR-2019-9

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333.

- 1. Agency: Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy
2. Agency umbrella and unit number: 02 392
3. Title of rule: Licensure of Manufacturers and Wholesalers
4. Chapter number assigned to the rule: Chapter 12
5. Date(s)/method(s) of notice: April 17, 2019 / SOS Weekly Notices of State Rulemaking, Electronic GovDelivery Subscribers, April 4, 2019 Maine Legislative Council
6. Date(s)/place(s) of hearing(s): May 8, 2019, 8:00 a.m., Central Conference Rm, ME Office of Professional & Occupational Regulation, Board of Pharmacy, 76 Northern Ave., Gardiner ME; comment period ended May 19, 2019
7. Type: [ ] new rule [x] partial amendment(s) of existing rule
[ ] suspension of existing rule [ ] repeal of rule [ ] emergency rule
[ ] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.



- 8. Name/phone of agency contact person: Geraldine L. Betts, Administrator (207) 624-8625
9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following
[x] Provisional adoption (prior to Legislative review) [ ] Final adoption
[ ] emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, R.Ph, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

Maine Board of Pharmacy on June 7, 2019
(name of agency) (date)

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed name & title: Joseph Bruno, R.Ph, Board President

11. Approved as to form and legality by the Attorney General on 6/20/19
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Michelle M. ROBERT AAG

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**392 MAINE BOARD OF PHARMACY**

**Chapter 12: LICENSURE OF MANUFACTURERS AND WHOLESALERS**

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**Summary:** This chapter sets forth license requirements for wholesalers, also known as wholesale pharmacies or wholesale drug distributors, and manufacturers.

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**1. Scope**

This chapter applies to manufacturers and wholesalers.

**2. Application for Licensure**

The manufacturer or wholesaler shall provide the following information on forms supplied by the board, along with such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the wholesaler or manufacturer;
2. All trade or business names used by the wholesaler or manufacturer;
3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the wholesaler or manufacturer for storing, handling and distributing prescription drugs.
4. Type of ownership or operation (i.e., partnership, corporation, limited liability company or sole proprietorship); and
5. The name(s) of the owner and/or operator of the wholesaler or manufacturer, including:
  - A. If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
  - B. If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not

Provisionally Adopted by the Maine Board of Pharmacy on June 6, 2019  
(Major Substantive Rulemaking)

organized under Maine law, a certificate of authority from the Maine Secretary of State if such certificate is required by 13-C M.R.S.A. §1501;

- C. If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
  - D. If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- 6. The DEA number;
  - 6-A. If the applicant is accredited by VAWD, proof of current accreditation.
  - 7. A list of all jurisdictions in which the manufacturer or wholesaler licensed as of the date of application to the board, along with the license number and license expiration date for each such jurisdiction;
  - 7-A. Disclosure of, and the final disposition document pertaining to, any disciplinary action taken against the manufacturer or wholesaler by a licensing or regulatory authority in any jurisdiction. If the applicant is accredited by VAWD, such disclosure and documentation need only pertain to the period of time subsequent to the wholesaler's initial accreditation or most recent annual renewal of accreditation.
  - 8. A copy of the most recent inspection report from the state in which the manufacturer or wholesaler is located. If a wholesaler is accredited by VAWD, this information need not be provided; and
  - 9. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees."

**3. Separate Applications for Separate Facilities**

The owner must file a separate application for each facility that manufactures or distributes wholesale prescription drugs. Applications need not be filed for business locations at which no manufacturing or distribution occurs.

**4. Minimum Qualifications**

The board will consider the following factors in determining the eligibility for licensure of persons who engage in the manufacture or wholesale distribution of drugs:

- 1. Subject to 5 M.R.S.A. §5301 *et seq.*, any findings by the board that the applicant has violated any federal, state or local laws relating to drug manufacturing or distribution;

Provisionally Adopted by the Maine Board of Pharmacy on June 6, 2019  
(Major Substantive Rulemaking)

2. Subject to 5 M.R.S.A. §5301 *et seq.*, any felony convictions of the applicant under federal, state or local laws;
3. The applicant's past experience in the manufacture or distribution of drugs;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Disciplinary action taken by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of drugs;
6. Compliance with previously granted licenses of any kind;
7. Compliance with the requirements to maintain and/or make available to the board or to federal, state or local law enforcement officials those records required to be maintained by manufacturers or wholesale drug distributors; and
8. Accreditation by VAWD.

**5. Change of Owner or Location; Change in Other Registration Information**

Upon a change of ownership, a manufacturer or wholesaler shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a manufacturer or wholesaler shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

**6. Operation of Manufacturer or Wholesaler**

A manufacturer or wholesaler shall comply with the rules of operation contained in Chapter 16, "Operation of Wholesalers and Manufacturers" of the board's rules.

**7. Exception to Prohibition Against Gifts to Practitioners**

The following definitions apply to terms contained in 32 M.R.S. § 13759, which constitute exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

1. For purposes of 32 M.R.S. § 13759(2)(A)(3), "modest meals and refreshments" means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quantity typically provided for attendees at the venue where the meeting or presentation occurs. For purposes of this section, minimal value means the cost of which is similar to that which a practitioner would pay when dining at his or her own expense as judged by local standards where the event is held.

Provisionally Adopted by the Maine Board of Pharmacy on June 6, 2019  
(Major Substantive Rulemaking)

2. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable honoraria” means cash, gratuity and/or a gift given to a practitioner in recognition for the Maine licensed practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of \$500 in retail value. Reasonable honoraria does not include or apply to:
- A. The fee for service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred; or
  - B. Where the manufacturer or wholesaler sponsoring the event does not participate or have influence over the selection of the practitioner chosen for the speaking engagement or payment for the services rendered by the practitioner.

The term “practitioner” does not include pharmacists.

3. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable expenses” means the reasonable and actual expenses for travel, lodging, and meals incurred by a practitioner and that are necessary in order for the practitioner to speak at a professional or educational conference sponsored by a manufacturer or wholesaler.

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STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

EFFECTIVE DATE:

November 8, 2004 - filing 2004-514

AMENDED:

March 11, 2012 – filing 2012-64

06/06/2019

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 BOARD OF PHARMACY

Chapter 12 LICENSURE OF MANUFACTURERS AND WHOLESALERS

PROVISIONALLY ADOPTED JUNE 6, 2019

**BASIS STATEMENT AND SUMMARY OF COMMENTS & RESPONSES**

**Basis Statement**

This Rule is proposed in response to Public Law 2017, Chapter 267, 32 M.R.S. § 13759 “An Act to Prohibit Certain Gifts to Health Care Practitioners”, directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. The proposed rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

The initial Notice of Proposed Rulemaking was published on April 17, 2019 with a public hearing of May 8, 2019 and written comment deadline of May 19, 2019 at 5:00 p.m.

**Response to Comments**

**List of Commenters:**

SUBMITTING WRITTEN COMMENTS:

- Shirlyn Adkins, 2621 Rochester, MN, (*Executive Director, of a nonprofit education physicians on neuromuscular diseases*)
- Kelsey Almy, Grand Junction, CO (*self-Almy*)
- Nicholas Argento, Columbia, MD (*self-Argento*)
- Betti Bandura, Thorofare, NJ (*self-Bandura*)
- Faith Bantivoglio, Thorofare, NJ (*self-Bantivoglio*)
- Robert Batte, Oldsmar, FL (*self-Batte*)
- Leanne Berger, Encinitas, CA (*self-Berger*)
- Christopher Bolwell, Alpharetta, GA (*self-Bolwell*)
- Michelle Bonnarens, Fort Wayne, TN (*self-Bonnarens*)
- Sara Brykalski, Chicago, IL (*self-Brykalski*)
- Donald Budenz, Chapel Hill, NC (*self-Budenz*)
- Courtney Burbridge, GA (*self-Burbridge*)
- John Burr, Bloomington, IL (*self-Bloomington*)
- Melissa Carter, Prairieville, LA (*self-Carter*)
- Karen Catino, Chicago, IL (*self-Catino*)
- Hope Carr, Stamford, CT (*self-Carr*)
- Michael Chang, Portland, OR (*self-Chang*)
- Ruth Cohen, Old Greenwich, CT (*self-Cohen*)
- Katlyn Cooper, Chicago, IL (*self-Cooper*)
- Kimberly Corbin, New York, NY (*self-Corbin*)
- Tracey Cross, Sheboygan Falls, CT (*self-Cross*)
- Tara Curran, Thorofare, NJ (*self-Curran*)
- Mindi Daiga, Mount Prospect, IL (*self-Daiga*)
- Jerri Davis, San Francisco, CA (*self-Davis*)
- Richard de Ramon, Mechanicsburg, PA, self (*de Ramon*)



06/06/2019

- Kathy Pitura, East Hartford, CT, self (*Pitura*)
  - Charles Pollack, Saint Davids, PA, self (*Clinician-scientist in academic practice-Pollack*)
  - Brittany Puster, Chicago, IL, self (*Puster*)
  - Tony Realini, Morgantown, WV, self (*International expert-Realini*)
  - Kristin Riday, Thorofare, NJ, self (*Riday*)
  - Nicolle Rochino, Edison, NJ, self (*Rochino*)
  - BJ Rose, Mantua, NJ, self (*Rose*)
  - Blair St. Armand, Elkridge, MD, self (*St. Armand*)
  - Lu Salazar, Washington, DC, self (*Salazar*)
  - Amy Schall, Saint Paul Park, MN, self (*Schall*)
  - Erin Schwarz, Foothill Ranch, CA, self (*Schwarz*)
  - Daniel Siegel, Saint James, NY, self (*Siegel*)
  - Rishi Singh, Shaker Heights, OH, self, Physician and educator (*Singh*)
  - Ashley Sipes, Shreveport, LA, self (*Sipes*)
  - Kimberly Sponza, Norwalk, CT, self (*Sponza*)
  - Heather Steelman, Denver, CO, self (*Steelman*)
  - Angela Still, Thorofare, NJ, self (*Still*)
  - Debi Susalka, Collegeville, PA, self (*Susalka*)
  - Paula Talbott, Columbia, MD, self (*Talbott, Columbia, MD*)
  - Paula Talbott, Huntingtown, MD, self (*Talbott, Huntingtown, MD*)
  - Heather Tarbox, Old Lyme, CT, self (*Tarbox*)
  - Renee Thomas, Camden, SC, self (*Thomas*)
  - Darla Thompson, Thorofare, NJ, self (*Thompson*)
  - Cynthia Tonallyay, RD, MBA, CCMEP, Redding, CT, self (*Tonallyay, Cynthia*)
  - Steve Tornallyay, Berkeley, CA, self (*Tornallyay, Steve*)
  - Wendy Turell, Montclair, NJ, self, CME professional (*Turell*)
  - Paul Tyndall, Wilmington, NC, self (*Tyndall*)
  - Meredith Vaccaro, Catonsville, MD, self (*Vaccaro*)
  - Mira Valkova, McLean, VA, self, Medical professional (*Valkova*)
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- Teri Valls, Miami, FL, self (*Valls*)
  - Jerrold Vitek, Roseville, MN, self (*Vitek*)
  - Kathy Whyte, Laurel, MD, self, Medical professional (*Whyte*)
  - Paula Williams, Malvern, PA, self (*Williams*)
  - Chad Williamson, Columbia, MD, self (*Williamson*)
  - Charles Willis, Rancho Mirage, CA, self, Hospital-based educational activities (*Willis*)
  - Andrew Antrobus, Sr. Director, Pfizer Government Relations, Pfizer, Inc., New York, NY, on behalf of Pfizer, Inc. (*Antrobus - Pfizer, Inc.*)
  - Brian Bohnenkamp, Nikki Reeves, Seth H. Lundy, King & Spalding LLP, Washington, DC, on behalf of the Ad Hoc Sunshine and State Law Compliance Group (*Ad-Hoc Bohnenkamp*)
  - Adrienne Brown, Windham, ME, self (*Brown*)
  - Terry Chang, MD, JD, Washington DC, and Chris L. White, COO and General Counsel, on behalf of Advanced Medical Technology Assoc. (AdvaMed) (*AdvaMed Chang*)
  - David C. Tilton, Portland ME, self (*Tilton*)
  - Howard Fienberg, VP Advocacy, Washington DC, on behalf of The Insights Association (*Insights-Fienberg*)
  - Jack Geisser, Director, Healthcare Policy, Medicaid, and State Initiatives, Washington DC, (on behalf of Biotechnology Innovation Organization (BIO), (*BIO-Geisser*))
  - Andrew Rosenberg, Sr. Advisor, CME Coalition, Washington DC, on behalf of CME Coalition (*CME Coalition-Rosenberg*)

money. More importantly, physicians in need of education on the latest developments in medicine will be deprived of training from the thought leaders who can provide it.” (Corbin)

- G. “Patients count on doctors to be up to date with the latest medical breakthroughs, and CME provides doctors with that knowledge – there is never a direct payment made.” (Daiga)
  - H. “Accredited education is highly regulated and the process of producing this education ensures that there is a firewall between any commercial/pharma support and the ultimate education provided to learners... We believe that \$250 is not enough in many cases to compensate the faculty physician experts that we ask to pull together the latest evidence-based curriculum.” (Davis)
  - I. “If the Maine bill is approved, personalized medical therapies that save lives and the future of medicine will be severely compensated.” (Derman)
  - J. “Please bear in mind that accredited CME honoraria are never directly paid by a pharmaceutical company to a speaker. All honoraria are paid by the accredited provider, so the “cash” is not coming from the manufacturer, it is coming from the CME provider... as an accredited provider of CME at a national level, I can say with 100% certainty that no one would give even one 60-minute presentation ... for \$250; let alone an annual maximum of \$250. To be well prepared we require speakers to review/edit the presentation at home, to be onsite 1 day prior to speaking for a final review/run through, and then to stick around after their talk for at least ½ day to answer questions.... 12 hours of work-time, plus the content review time at home, and all for \$250 per year?” (Fountain)
  - K. “...\$250 is simply not enough compensation for what we are asking [presenters] to do – leave their office, in most cases for several days, and leave their families – for a 2-hour presentation. The rest of us are compensated by our employers for this time away – our faculty are not. This proposal is completely ludicrous.” (Groves)
  - L. “It is in Maine’s best interest to not stifle but to support accredited CME programs by allowing them to utilize respected faculty... as currently drafted, we believe this proposed rule does not meet that need by failing to allow for CME providers to reasonably compensate Maine faculty for work involved in delivering accredited educational programs. In short, the proposed rule disincentivizes Maine faculty members from participating in CME activities. Eliminating the proposed rule’s strict limitation on the provision of honoraria to faculty members participating in accredited CME activities will allow physicians to continue to participate in CME without the risk of conflict-of-interest Maine rightly seeks to curtail.” (CME Coalition-Rosenberg)
  - M. “I am disabled with Multiple Sclerosis, anxiety and depression... I rely on the free programs sponsored by the drug companies for straight forward educational and social support... Don’t limit doctor educational consulting, clinical research or educational conferences and other opportunities for patients and doctors in Maine to educate themselves...” (Brown)
  - N. Mr. Tilton states that he and his wife attend patient educational programs about various MS drugs in support of his wife who has MS and feels that the \$250 honoraria cap for doctors is not realistic to cover the presenter’s costs and expenses. (Tilton)
2. Brian Bohnenkamp, Nikki Reeves, Seth H. Lundy, King & Spalding LLP, Washington, DC, on behalf of the Ad Hoc Sunshine and State Law Compliance Group (*Ad-Hoc Bohnenkamp*)

Andrew Antrobus, Sr. Director, Pfizer Government Relations, Pfizer, Inc., New York, NY, on behalf of Pfizer, Inc. (*Antrobus - Pfizer, Inc.*) “We support the recommendations submitted by the Biotechnology Innovation Organization (“BIO”) and the Ad Hoc Sunshine and State Law Compliance Group.”

A. WRITTEN COMMENT: REASONABLE HONORARIA, following is a brief summation.

“To help alleviate an unnecessary chilling of Maine practitioners’ participation in such third-party educational events and programs that are sponsored by manufacturers and wholesalers, the Ad Hoc Group requests that the Board make one of the following revisions to the proposed definition of “reasonable honoraria”:

“Option 1: Remove any express dollar limitation on practitioners’ receipt of honoraria.

Option 2: If the Board is not amendable to removing a specific dollar limitation, then the Ad Hoc Group requests that the Board clarify that the dollar limitation does not apply to professional or educational conferences sponsored by a manufacturer or wholesaler where the manufacturer or wholesaler does not select or influence the selection of which practitioners are speakers, as follows:"

(Add to section 7(2)) The annual dollar limit shall not apply to professional or educational conferences sponsored by a manufacturer or wholesaler where the manufacturer or wholesaler does not select or influence the selection of which practitioners are speakers."

**B. WRITTEN COMMENT: MODEST MEALS AND REFRESHMENTS, following is a brief summation.**

"To help avoid confusion and ensure consistency with the statute, the Ad Hoc Group respectfully requests that the Board make the following minor revision to the proposed definition to help avoid potential confusion":

Suggest amending section 7(1) For purposes of 32 M.R.S. §13759(2)(A)(3), "modest meals and refreshments" means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quality typically provided for conference attendees at the venue where the meeting or presentation occurs.

3. Jack Geisser, Director, Healthcare Policy, Medicaid, and State Initiatives, Washington DC, (on behalf of Biotechnology Innovation Organization (BIO), *(BIO-Geisser)*)

**A. WRITTEN COMMENT: MODEST MEALS AND REFRESHMENTS, following is a brief summation.**

Under the proposed definition of modest meals and refreshments, there would be no basis to determine what is a typical meal in that particular venue, while being "a venue and manner conducive to information communication," it is not a "conference" venue. The Board should consider the Commonwealth of Massachusetts definition, which defines, "modest meals and refreshments" as food and/or drinks provided by or paid for by a pharmaceutical manufacturer representative... that as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.

**B. WRITTEN COMMENT: HONORARIA, following is a brief summation.**

"BIO believes a better alternative to the arbitrary \$250 cap on honoraria, would be to impose a "fair market value" (FMV) threshold for honoraria instead. This would ensure that the state can attract top professionals and maintain high levels of patient care in the State of Maine. Furthermore, the Board must make it clear that the cap would not apply to out-of-state practitioners."

**C. WRITTEN COMMENT: BONA FIDE SERVICE ARRANGEMENTS, following is a brief summation.**

"We are concerned that the statute, together with the regulations as drafted, does not explicitly exempt research. Nevertheless, we interpret the statute as to not apply to bona fide service arrangements between manufacturers and licensed practitioners/prescribers in Maine. These types of arrangements include but are not limited to research or clinical trials, as well as participation in scientific advisory boards. They are contractual arrangements that provide compensation based upon fair market value (FMV) for services rendered. These payments are not "gifts" as intended by the statute."

4. Terry Chang, MD, JD, Washington DC, on behalf of Advanced Medical Technology Assoc. (AdvaMed) *(AdvaMed Chang)*

A. WRITTEN COMMENT: REASONABLE HONORARIA, following is a brief summation.

Amend as follows: For purposes of 32 M.R.S. §13759(2)(C), “reasonable honoraria” means cash and/or gift given to a practitioner in return for the practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of \$250 in retail value.

5. Howard Fienberg, VP Advocacy, Washington DC, on behalf of The Insights Association (*Insights-Fienberg*)

A. WRITTEN COMMENT: MARKETING RESEARCH STUDIES, following is a brief summation.

“[The] 2017 law has inadvertently banned respondent incentives for practitioners who participate in pharmaceutical marketing research studies, even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not aware of which practitioners participated. That is because pharmaceutical manufacturers’ compliance departments take the most conservative reading of such laws: if marketing research incentives are not explicitly exempted or excluded, those compliance departments will assume they are prohibited as “gifts.” Such has been the case across the industry since Maine passed this law two-years ago.”

“Except for two states (Vermont and Maine), all permit such research and have little to no restrictions on marketing research incentive payments to the practitioners.”

This commenter suggests adding the following to the proposed rule:

For purposes of 32 M.R.S. § 13759, a “gift” does not include a payment to a practitioner for participation in bona fide marketing research conducted by a third party, if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating practitioner.

“Bona fide marketing research” means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant’s attitudes or behavior.

Or, “the simpler approach of clarifying that independent third-party marketing research companies are not “agents” of a manufacturer.”

For purposes of 32 M.R.S. § 13759(1), to the extent that a marketing research company does not engage in detailing, promotional activities, or other marketing of prescription drugs or biologics, such company, by definition, is not considered a manufacturer’s agent.

6. Amon Purinton, on behalf of Northern Light Health [Maine] (*Northern Light Health-Purinton*)

*Public hearing testimony: The scope of the rule applies generally to prohibit gifts to “practitioners,” which as defined in law is defined to reference prescribers. The proposed rule as written could be construed to include pharmacists. Mr. Purinton also raised question on what “honoraria” is meant for purposes of this proposed rule, which does not reflect the Board’s discussion at a prior meeting where the Board agreed that honoraria does not include the speaker’s fee for his or her presentation, but rather a token or gift bag above and beyond the speaker’s fee.*

## BOARD'S RESPONSE TO COMMENTS

The Board appreciates all comments received. The following is the Board's response to all comments.

### 1. BOARD'S RESPONSE TO COMMENTS ON MODEST MEALS AND REFRESHMENTS

The Board agrees with commenters on the need for greater clarification on what the Board considers "minimal value" in relation to modest meals and refreshments and will amend the rule to clarify that "minimal value" means the cost of which is similar to that which a practitioner would pay when dining at his or her own expense as judged by local standards where the event is held.

The Board agrees to removing the word "conference" in Section 7, (1) for consistency with 32 M.R.S. §13759, Section 2(A)(3).

### 2. BOARD'S RESPONSE TO COMMENTS ON REASONABLE HONORARIA

The Board does not agree with comments to remove any express dollar limitation or to leave the honoraria to fair market value. The Board agrees that the \$250.00 may not be sufficient and agrees to place the honoraria cap at \$500.00. The Board agrees that the honoraria is a gift or gratuity in recognition of the practitioner's presentation and does not include fee for service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred.

The Board agrees that if a manufacturer or wholesaler sponsors a conference or meeting event with a dollar donation, and the manufacturer or the wholesaler does not and is not a participant in the selection of the practitioner chosen for the speaking engagement, nor does it influence or pay the practitioner directly, the honoraria limitation does not apply to such professional or educational meeting or presentation events.

The Board agrees on the need to clarify that "practitioner" does not include pharmacists. The term "practitioner" is defined under 32 M.R.S. §13702-A, Section 29 as, "...an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice." In addition, the Board agrees that this rule applies to Maine licensed practitioners and does not apply to practitioners licensed outside Maine.

### 3. BOARD'S RESPONSE TO COMMENTS ON BONA FIDE MARKETING RESEARCH

Commenters expressed concern that,

"[The] 2017 law has inadvertently banned respondent incentives for practitioners who participate in pharmaceutical marketing research studies, even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not aware of which practitioners participated."

"We are concerned that the statute, together with the regulations as drafted, does not explicitly exempt research. Nevertheless, we interpret the statute as to not apply to bona fide service arrangements between manufacturers and licensed practitioners/prescribers in Maine."

- BOARD'S RESPONSE: The Board understands the spirit of these comment. Pursuant to 32 M.R.S. §13759, the Maine Legislature directs the Board to define by rule "modest meals and refreshments" and "giving reasonable honoraria." Legislature. The Board does not believe the law prohibits payment to a practitioner for services rendered and would not be a matter subject to Board action. Addressing or proposing something other than a gift is not within the purview of the Board and a matter for the commenter to address directly with the Maine Legislature.

## Betts, Geraldine L

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**From:** Betts, Geraldine L  
**Sent:** Friday, July 12, 2019 4:15 PM  
**To:** Wismer, Don  
**Subject:** Pharmacy (02 392) - PROVISIONAL Adoption of Rules - Chapter 21 Licensure of Manufacturers and Wholesalers  
**Attachments:** Provisionally Adopted06062019.docx; MAPA 4 Notice of Agency Rule-making Adoption.docx

Good Afternoon Don,

This rulemaking is related to rules on the Exception to Prohibition Against Gifts to Practitioners and is a Major-Substantive Rule. We were unable to get this submitted in time for the 1<sup>st</sup> session of the 129<sup>th</sup> and am submitting it now.

I have not done a Major-Substantive rule submission, but have read all of the directions online from the Secretary of State website, the law on MS rulemaking and directions on the Legislative Council's website. I hope I get this right.

- 1) Per the directions on the SOS website, if I understood correctly, the attached documents are the ones you require in electronic form. The documents I am sending by interoffice mail today (mail pick not till Monday) are: 1 MAPA-4, 2 signed copies of MAPA-1, 2 copies of the rule, and 2 copies each of the Basis Statement and Response to Comments, Fact Sheet and Checklist.

I am also submitting by interoffice mail the required documents pursuant to the Legislative Council's checklist <http://legislature.maine.gov/doc/1819>

Please let me know if I missed anything. Thank you and have a nice weekend.

Jeri



*Geraldine "Jeri" L. Betts, Administrator*

Maine Office of Professional and Occupational Regulation  
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**All Licensing Inquiries:**

Barbering and Cosmetology Program (207-624-8579)  
Board of Complementary Health Care Providers (207-624-8620)  
(Acupuncturists, Naturopathic Doctors, Professional Midwives)  
Board of Chiropractic Licensure (207-624-8620)  
Board of Pharmacy (Non Resident Companies 207-624-8686) (ME Companies & Individuals (207-624-8620)  
Board of Examiners in Physical Therapy (207-624-8620)  
Board of Veterinary Medicine (207-624-8620)  
**Board Agendas, Meetings, Business Matters & Licensing Supervisor:** (207-624-8651)

# Rule-Making Fact Sheet

(5 MRS §8057-A)

AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy.

CHAPTER NUMBER AND RULE TITLE: Chapter 12 "Licensure of Manufacturers and Wholesalers".

STATUTORY AUTHORITY: 32 M.R.S. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

DATE, TIME AND PLACE OF PUBLIC HEARING: May 8, 2019, 8:00 a.m., 76 Northern Avenue, Gardiner, Maine 04333, Central Conference Room.

COMMENT DEADLINE: May 19, 2019 by 5:00 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: 2017 Public Law, Chapter 267, 32 M.R.S. §13759, "An Act to Prohibit Certain Gifts to Health Care Practitioners" directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE?  YES  NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [see §8057-A(1)(B) &(D)]  
This chapter establishes procedures and standards for licensure, reporting requirements and guidelines specific to pharmacy wholesalers and manufactures.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]  
Title 42 Code of Federal Regulations; Sunshine Act; legislation enacted in other states; staff input; definitions in current Maine Board of Pharmacy rules; Regulations from the Maine Board of Medicine; and American Code of Medical Ethics Opinion 9.6.2.

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)] None.

**FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:**

ECONOMIC IMPACT, IF QUANTIFIABLE IN MONETARY TERMS:  
[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

*Note: If necessary, additional pages may be used.*

# Administrative Procedure Act

## CHECKLIST

Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

Chapter Number and Title of Rule: Chapter 12, Licensure of Manufacturers and Wholesalers

### PROPOSED RULE:

1. Was this rule listed on the last regulatory agenda? **Yes**
2. Date of notification of: **April 17, 2019** Anyone on mailing list: **Electronic GovDelivery Subscribers**  
Any trade, industry or professional group \_\_\_\_\_  
Any trade publications \_\_\_\_\_
3. Date Notice of Rulemaking Proposal (MAPA-3) sent to Secretary of State: **April 4, 2019** \_\_\_\_\_
4. Date Fact Sheet sent to Executive Director of Legislative Council: **April 4, 2019** \_\_\_\_\_
5. Date of publication in Secretary of State's rule-making ad.: **April 17, 2019** \_\_\_\_\_
6. Date of hearing(s): **May 8, 2019 at 8:00 a.m.** 7. Comment deadline: **May 19, 2019 by 5:00 p.m.**

### ADOPTED RULE:

8. Was comment deadline extended or comment period reopened? **No** \_\_\_\_\_  
If yes, date of second notice publication in Secretary of State's rule-making ad: **n/a** \_\_\_\_\_
9. Is adopted rule consistent with what was proposed? **Yes** \_\_\_\_\_  
(If not, please address the changes in the comments and responses section of your filing.)
10. Is the person signing the Certification Statement (MAPA-1, #9) authorized to do so as stated in your statutes or in 5 MRSA, c.71? **Yes** \_\_\_\_\_
11. Was the rule adopted within 120 days of the comment deadline? **Yes, by vote of the Board of Pharmacy on June 6, 2019**
12. Was the rule approved and signed by the Office of the Attorney General within 150 days of the comment deadline? **Yes, June 20, 2019**
13. Is a Basis Statement included? **Yes** \_\_\_\_\_ Is a copy of the Fact Sheet included? **Yes** \_\_\_\_\_  
Are comments, with names and organizations, and your responses included? **Yes** \_\_\_\_\_



# Notice of Agency Rule-making Adoption

**AGENCY:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

**CHAPTER NUMBER AND TITLE:** Chapter 12, Licensure of Manufacturers and Wholesalers

**ADOPTED RULE NUMBER:** **20xx.xxx**  
(LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE)

### CONCISE SUMMARY

2017 Public Law, Chapter 267, 32 M.R.S. §13759, "An Act to Prohibit Certain Gifts to Health Care Practitioners" directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

On June 6, 2019, the Maine Board of Pharmacy voted to provisionally adopt these rules, which pursuant to 32 MRS § 13759 are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

NOT NEEDED  
FOR A PROV.  
ADOPTION

**EFFECTIVE DATE:**  
(TO BE FILLED IN BY SECRETARY OF STATE)

**AGENCY CONTACT PERSON:** Geraldine L. Betts, Administrator

**AGENCY NAME:** Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation

**ADDRESS:** 35 State House Station, Augusta ME 04333

**TELEPHONE:** 207-624-8625

## STATE OF MAINE

IN THE YEAR OF OUR LORD

TWO THOUSAND TWENTY

H.P. 1338 - L.D. 1872

**Resolve, Regarding Legislative Review of Portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a Major Substantive Rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy**

**Emergency preamble.** Whereas, acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

**Whereas,** the Maine Revised Statutes, Title 5, chapter 375, subchapter 2-A requires legislative authorization before major substantive agency rules may be finally adopted by the agency; and

**Whereas,** a major substantive rule has been submitted to the Legislature for review; and

**Whereas,** immediate enactment of this resolve is necessary to record the Legislature's position on final adoption of the rule; and

**Whereas,** in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore, be it

**Sec. 1. Adoption. Resolved:** That final adoption of portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a provisionally adopted major substantive rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy that has been submitted to the Legislature for review pursuant to the Maine Revised Statutes, Title 5, chapter 375, subchapter 2-A, is authorized.

**Emergency clause.** In view of the emergency cited in the preamble, this legislation takes effect when approved.

## Notice of Agency Rule-making Adoption

**AGENCY:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

**CHAPTER NUMBER AND TITLE:** Chapter 12, Licensure of Manufacturers and Wholesalers

**ADOPTED RULE NUMBER:** **20xx.xxx**  
(LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE)

### CONCISE SUMMARY

2017 Public Law, Chapter 267, 32 M.R.S. §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners” directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

On June 6, 2019, the Maine Board of Pharmacy voted to provisionally adopt these rules, which pursuant to 32 MRS § 13759 are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

On February 12, 2020, the Committee on Health Coverage, Insurance and Financial Services reported out LD 1872 (Emergency Preamble, Resolve, Regarding Legislative Review of Portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a Major Substantive Rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy) Ought to Pass with no changes to the provisionally adopted rule and finally passed by the Maine Legislature on February 25, 2020.

On March 9, 2020, Governor Mills signed 2020 Public Law Chapter 115 (LD 1872) Emergency Preamble, Resolve, Regarding Legislative Review of Portions of Chapter 12: Licensure of Manufacturers and Wholesalers, a Major Substantive Rule of the Department of Professional and Financial Regulation, Maine Board of Pharmacy.

**EFFECTIVE DATE:**  
(TO BE FILLED IN BY SECRETARY OF STATE)

**AGENCY CONTACT PERSON:** Geraldine L. Betts, Administrator

**AGENCY NAME:** Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation

**ADDRESS:** 35 State House Station, Augusta ME 04333

**TELEPHONE:** 207-624-8625

# Rulemaking Cover Sheet

MAPA-1

**TO:** Secretary of State  
**ATTN:** Administrative Procedure Officer,  
State House Station 101, Augusta, Maine 04333.

1. **Agency:** Maine Department of Professional and Financial Regulation  
Office of Professional and Occupational Regulation  
Board of Pharmacy
2. **Agency umbrella and unit number:** 02-392  
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Licensure of Manufacturers and Wholesalers
4. **Chapter number assigned to the rule:** Chapter 12  
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** April 17, 2019 / SOS Weekly Notices of State Rulemaking, Electronic Gov Delivery
6. **Date(s)/place(s) of hearing(s):** May 8, 2019, 8:00 a.m., Central Conference Rm, ME Office of Professional and Occupational Regulation, Board of Pharmacy, 76 Northern Ave., Gardiner ME; comment period ended May 19, 2019
7. **Type:**  new rule  partial amendment(s) of existing rule  
 suspension of existing rule  repeal of rule  emergency rule  
 repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.
8. **Name/phone of agency contact person:** Geraldine L. Betts, Administrator / 207-624-8625
9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**  
 **Provisional adoption** (prior to Legislative review)  **Final adoption** (Major Substantive)  
 **emergency adoption of major-substantive rule**

10. **Certification Statement:** I, Joseph Bruno, R.Ph., hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

Maine Board of Pharmacy on \_\_\_\_\_  
(name of agency) (date)

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

**Signature:** \_\_\_\_\_  
(original signature, personally signed by the head of agency)

**Printed name & title:** Joseph Bruno, R.Ph., Board President

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**11. Approved as to form and legality by the Attorney General on \_\_\_\_\_.**

(date)

**Signature \_\_\_\_\_.**

(original signature, personally signed by an Assistant Attorney General)

**Printed Name: \_\_\_\_\_.**

**Chapter 12: LICENSURE OF MANUFACTURERS AND WHOLESALERS**

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**Summary:** This chapter sets forth license requirements for wholesalers, also known as wholesale pharmacies or wholesale drug distributors, and manufacturers.

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**1. Scope**

This chapter applies to manufacturers and wholesalers.

**2. Application for Licensure**

The manufacturer or wholesaler shall provide the following information on forms supplied by the board, along with such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the wholesaler or manufacturer;
2. All trade or business names used by the wholesaler or manufacturer;
3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the wholesaler or manufacturer for storing, handling and distributing prescription drugs.
4. Type of ownership or operation (i.e., partnership, corporation, limited liability company or sole proprietorship); and
5. The name(s) of the owner and/or operator of the wholesaler or manufacturer, including:
  - A. If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
  - B. If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not

organized under Maine law, a certificate of authority from the Maine Secretary of State if such certificate is required by 13-C M.R.S.A. §1501;

- C. If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
  - D. If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- 6. The DEA number;
  - 6-A. If the applicant is accredited by VAWD, proof of current accreditation.
  - 7. A list of all jurisdictions in which the manufacturer or wholesaler licensed as of the date of application to the board, along with the license number and license expiration date for each such jurisdiction;
  - 7-A. Disclosure of, and the final disposition document pertaining to, any disciplinary action taken against the manufacturer or wholesaler by a licensing or regulatory authority in any jurisdiction. If the applicant is accredited by VAWD, such disclosure and documentation need only pertain to the period of time subsequent to the wholesaler's initial accreditation or most recent annual renewal of accreditation.
  - 8. A copy of the most recent inspection report from the state in which the manufacturer or wholesaler is located. If a wholesaler is accredited by VAWD, this information need not be provided; and
  - 9. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees."

### **3. Separate Applications for Separate Facilities**

The owner must file a separate application for each facility that manufactures or distributes wholesale prescription drugs. Applications need not be filed for business locations at which no manufacturing or distribution occurs.

### **4. Minimum Qualifications**

The board will consider the following factors in determining the eligibility for licensure of persons who engage in the manufacture or wholesale distribution of drugs:

- 1. Subject to 5 M.R.S.A. §5301 *et seq.*, any findings by the board that the applicant has violated any federal, state or local laws relating to drug manufacturing or distribution;

2. Subject to 5 M.R.S.A. §5301 *et seq.*, any felony convictions of the applicant under federal, state or local laws;
3. The applicant's past experience in the manufacture or distribution of drugs;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Disciplinary action taken by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of drugs;
6. Compliance with previously granted licenses of any kind;
7. Compliance with the requirements to maintain and/or make available to the board or to federal, state or local law enforcement officials those records required to be maintained by manufacturers or wholesale drug distributors; and
8. Accreditation by VAWD.

**5. Change of Owner or Location; Change in Other Registration Information**

Upon a change of ownership, a manufacturer or wholesaler shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a manufacturer or wholesaler shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

**6. Operation of Manufacturer or Wholesaler**

A manufacturer or wholesaler shall comply with the rules of operation contained in Chapter 16, "Operation of Wholesalers and Manufacturers" of the board's rules.

**7. Exception to Prohibition Against Gifts to Practitioners**

The following definitions apply to terms contained in 32 M.R.S. § 13759, which constitute exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

1. For purposes of 32 M.R.S. § 13759(2)(A)(3), "modest meals and refreshments" means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quantity typically provided for attendees at the venue where the meeting or presentation occurs. For purposes of this section, minimal value means the cost of which is similar to that which a practitioner would pay when dining at his or her own expense as judged by local standards where the event is held.



2. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable honoraria” means cash, gratuity and/or a gift given to a practitioner in recognition for the Maine licensed practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of \$500 in retail value. Reasonable honoraria does not include or apply to:
- A. The fee for service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred; or
  - B. Where the manufacturer or wholesaler sponsoring the event does not participate or have influence over the selection of the practitioner chosen for the speaking engagement or payment for the services rendered by the practitioner.

The term “practitioner” does not include pharmacists.

3. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable expenses” means the reasonable and actual expenses for travel, lodging, and meals incurred by a practitioner and that are necessary in order for the practitioner to speak at a professional or educational conference sponsored by a manufacturer or wholesaler.

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STATUTORY AUTHORITY: 32 M.R.S.A- §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

EFFECTIVE DATE:

November 8, 2004 - filing 2004-514

AMENDED:

March 11, 2012 – filing 2012-64