

Appendix I

105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct

970.001: Purpose

105 CMR 970.000 is set forth for the purpose of interpreting and to implementing M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care. 105 CMR 970.000 is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners. Pursuant to M.G.L. c. 111N, the regulation seeks to accomplish these objectives consistent with the letter and the spirit of M.G.L. c. 111N, without compromising companies' legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

970.002: Regulatory Authority

105 CMR 970.000 is adopted under the authority of M.G.L. c.111, s.3 and M.G.L. c.111N.

970.003: Citation

105 CMR 970.000 shall be known, and may be cited, as The Pharmaceutical and Medical Device Manufacturer Code of Conduct or the Marketing Code of Conduct.

970.004: Definitions

The following terms as used in 105 CMR 970.000 shall have the following meanings, unless the context or subject matter clearly require a different interpretation:

"Authorized entity," the attorney general, the district attorney with jurisdiction over a violation, or the department of public health.

"Biologic," a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product, or analogous product, as defined by Section 351 of the Public Health Service Act applicable to the prevention, treatment, or cure of a disease or condition of human beings and regulated as a drug under the Federal Food, Drug, and Cosmetic Act.

"Bona fide services," an arrangement for consulting services for services, including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and

presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including U.S. Food and Drug Administration (“FDA”) required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the consulting services and characterized by the following factors:

- a legitimate need for the consulting services clearly identified in advance;
- a connection between the competence and expertise of the consultant health care practitioner and the purpose of the arrangement;
- the number of health care professionals-practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by consultantsthe health care practitioner; and
- the venue and circumstances of any meeting with consultants-the health care practitioner is conducive to the consulting services and activities related to the services are the primary focus of the meeting; and-
- the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company’s sales personnel.

“Bona fide services” also include the licensing of intellectual property when such arrangements are formalized in a written agreement based on fair market value.

“Charitable donation,” the provision of financial support to a 501(c)(3) or the in-kind provision of drugs, biologics or medical devices for charity care of patients.

“Clinical trial,” a genuine research project involving a drug or medical device which uses volunteer human research subjects to that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation of treatment of a disease or health condition, or to evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and/or, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board (“IRB”) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.

“Covered recipient,” A person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth, including a physician, hospital, nursing home, pharmacist, health benefit plan administrator, wholesaler licensed to sell or distribute prescription drugs or medical devices or a health care practitioner. A person who otherwise meets this definition but is a bona fide employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.

“Conference or Meeting,” any convening where responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the

~~event's organizers of the conference or meeting~~ in accordance with their guidelines, held in a venue that is appropriate and conducive to informational communication and training about medical information, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

"Department," the department of public health.

"Genuine Research Project," a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published freely by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry.

"Health care practitioner", a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, A bona fide full time employees and boardmembers of a pharmaceutical or medical device manufacturers are not a health care practitioners.

"Hospital Setting," (a) a hospital (b) academic medical center or (c) pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory ~~and or~~ to provide medical training ~~that uses human tissue or cadavers,~~ on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.

~~"Marketing Code of Conduct," practices and standards that govern the marketing and sale of prescription drugs, biologics, or medical devices by a pharmaceutical or medical device manufacturing company to a covered recipient~~

"Medical device," an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (3) intended to affect the structure or function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

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“Non-faculty,” a health care practitioner who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education (“CME”) event, third-party scientific or educational conference, or professional meeting.

~~“Participates in a Commonwealth Health Care Program,” does business, either directly or indirectly, with a program for which the commonwealth purchases or provides reimbursement for pharmaceuticals, biologics, or medical devices, including, but not limited to MassHealth, the Group Insurance Commission, the Massachusetts State Employees Retirement Board, and UMASS Correctional Health or the contractual medical provider for the Department of Corrections.~~

“Person,” a business, individual, corporation, union, association, firm, partnership, committee or other organization.

~~“Pharmaceutical or medical device manufacturer agent,” a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices ; provided, however, that “pharmaceutical or medical device manufacturer agent” shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he or she is licensed, a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacist registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company, a pharmaceutical or medical device marketer or any other person who for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, biologic or medical device, or category of prescription drugs, biologics, or medical devices; provided, however, that “pharmaceutical or medical device manufacturer agent” shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he is licensed.~~

“Pharmaceutical or medical device manufacturing company,” any entity that:

- (a) ~~participates in a commonwealth health care program and is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or~~

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independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or

- (b) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices;

provided, however, that “pharmaceutical or medical device manufacturing company” shall not include a health care practitioner, physician practice, home health agency, hospital licensed under M.G.L. c. 1114, s. 51, a wholesale drug distributor licensed under M.G.L. c. 112, s. 36A or a retail pharmacist registered under M.G.L. c. 112, s. 37-39C.

~~“Pharmaceutical or medical device marketer,” a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company that participates in a commonwealth health care program, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices; provided, however, that “pharmaceutical or medical device marketer” shall not include a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacist registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.~~

~~“Physician,” a person licensed to practice medicine by the board of registration in medicine under section 2 of chapter 112 who prescribes prescription drugs, or the physician’s employees or agent~~

~~“Prescription drugs,” drugs upon which the manufacturer or distributor has placed~~

~~or is required by federal law and regulations to place the following or a comparable warning: “Caution federal law prohibits dispensing without prescription.”~~

“Sales and marketing activities,” for the purposes of disclosure under 105 CMR 970.009, sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of an individual health care practitioner covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose and the provision of any fee,

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payment, subsidy or other economic benefit with a value of at least \$50 to a health care practitioner.

~~for any purpose other than reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial.~~ Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a covered recipient except as follows: Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan's formulary.

970.005: General Requirements

1. **By July 1, 2009, each pharmaceutical or medical device manufacturing company that employs or contracts with a person to sell or market prescription drugs or medical devices pharmaceutical or medical device manufacturer agent in the commonwealth shall:**
 - a. ~~adopt and comply with the most recent Marketing a marketing cCode of cConduct in compliance with the requirements of 105 C.M.R. 970.000, as adopted by the Department pursuant to 105 C.M.R. 970.000;~~
 - b. **adopt and submit to the Department a description of a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the mMarketing cCode of cConduct. The training program must:**
 - i. **ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of:**
 1. **the mMarketing cCode of cConduct,**
 2. **general science, and**

3. product-specific information to provide accurate, up-to-date information, consistent with state law and FDA requirements; and
 - ii. provide for regular assessments of ~~representatives persons~~ who are employed by or acting on behalf of the companies to ensure that they comply with ~~the requirements of the Marketing Code of Conduct and~~ 105 C.M.R. 970.000 and other relevant company policies.
 - c. certify to the Department to the best of the company's knowledge, ~~information and belief that it is in compliance with the Marketing Code of Conduct~~ 105 C.M.R. 970.000;
 - d. adopt and submit to the Department policies and procedures for investigating ~~instances of non-compliance with the Marketing Code of Conduct~~ 105 C.M.R. 970.000, taking corrective action in response to noncompliance and reporting ~~of instances of non-compliance to the appropriate state authorities; and~~
 - e. submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for ~~certifying compliance with~~ 105 C.M.R. 970.000 and ~~operating implementing, monitoring, and enforcing the company's mMarketing eCode of eConduct.~~
2. Each pharmaceutical manufacturing company that uses non-patient identified prescriber data to facilitate communications with health care practitioners ~~must~~ shall:
 - a. maintain the confidential nature of prescriber data;
 - b. develop policies regarding the use of the data;
 - c. educate employees and agents about these policies;
 - d. ~~maintain designate~~ an internal contact person to handle inquiries regarding the use of the data;
 - e. identify appropriate disciplinary actions for misuse of the data; and
 - f. comply with the request of any health care practitioner not to make his or her prescriber data available to company sales representatives.

- g. Before utilizing health care practitioner prescriber data for marketing purposes, manufacturers must give health care practitioners the opportunity to request that their prescriber data :
 - i. be withheld from company sales representatives, and
 - ii. not be used for marketing purposes.

- h. Nothing in this section shall prohibit pharmaceutical manufacturing companies from using prescriber data to:
 - i. impart important safety and risk information to prescribers of a particular drug or device;
 - ii. conduct research;
 - iii. comply with FDA mandated risk management plans that require manufacturers to identify and interact with health care practitioners who prescribe certain drugs or devices; or
 - iv. track adverse events of marketed drugs, biologics or devices.

- 3. In all speaker and commercial consultant contracts, pharmaceutical manufacturing companies ~~must~~ shall require any health care practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.

- 4. Beginning on July 1, 2010, and annually on or before July 1 of each year thereafter, each pharmaceutical and medical device manufacturing company must certify to the Department that it has conducted annual audits to monitor compliance with the Marketing Code of Conduct 105 C.M.R. 970.000.

970.006: Provision of Meals Under the Marketing Code of Conduct

- 1. Except as otherwise provided in 105 CMR 970.000, no pharmaceutical or medical device manufacturing company that employs or contracts with a person to sell or market prescription drugs, biologics or medical devices pharmaceutical or medical device manufacturer agent in the commonwealth may provide or pay for meals for health care practitioners that:
 - a. are part of an entertainment or recreational event;

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- b. are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present;
 - c. are offered, consumed, or provided outside of the health care practitioner's office or a hospital setting; or
 - d. are provided to a healthcare practitioner's spouse or other guest.
2. Meals provided to health care practitioners in compliance with 105 CMR 970.006 must be modest and occasional in nature.

970.007: Continuing Medical Education ("CME"), Third-Party Scientific or Educational Conferences, or Professional Meetings

1. No pharmaceutical or medical device manufacturing company that ~~employs or contracts with a person to sell or market prescription drugs, biologics or medical devices~~ a pharmaceutical or medical device manufacturer in the commonwealth may provide:
- a. financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor.
 - b. funding to compensate for the time spent by health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;
 - c. payment for meals directly to a health care practitioner at any CME event, third-party scientific or educational conferences, or professional meetings, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants
 - d. sponsorship or payment for CME, also known as independent medical education, that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education ("ACCME") or equivalent commercial support standards of the relevant continuing education accrediting body, or that provides payment directly to a health care practitioner.

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2. A pharmaceutical manufacturing company shall separate its CME grant-making functions from its sales and marketing departments.
3. A pharmaceutical manufacturing company shall not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.

4. Nothing in this section these regulations shall prohibit:

~~a. financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend educational conferences, provided that:~~

~~the educational conference is a major educational, scientific, or policy-making meeting of a national, regional, or specialty medical association,~~

~~the selection of individuals who will receive funds is made by the academic or training institution, and~~

~~no grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items are provided or offered to a health care practitioner in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical device~~

ab. compensation or reimbursement made to a health care practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, provided that the payment:

1. is reasonable;
2. is based on fair market value; and
3. complies with the standards for commercial support as established by the relevant accredited continuing medical education provider accreditation entity.

be. sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers.

c. the use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences.

970.008: Other Payments to Health Care Practitioners

1. ~~No pharmaceutical or medical device manufacturing company that employs or contracts with a person to sell or market prescription drugs, biologics or medical devices a pharmaceutical or medical device manufacturer agent in the commonwealth may provide:~~
 - a. entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing company;
 - b. payments of any kind including cash or cash equivalents, equity, “in kind” or tangible items including any “complimentary” items such as pens, coffee mugs, gift cards, etc. to health care practitioners either directly or indirectly, except as compensation for bona fide services;
 - c. any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices;
 - d. any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or “kickback” that is prohibited under applicable federal or state “fraud and abuse” laws or regulations including the federal “Anti-Kickback Statute” (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws such as M.G.L. c. 118E, s. 41 and M.G.L. c. 175H, s. 3.
2. ~~Nothing in this section~~ these regulations shall prohibit the following payments:
 - a. ~~Reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial~~ bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by the health care practitioner directly as a result of the performance of such services, where the compensation and reimbursement is specified in, and paid for under, a written sponsored research agreement;
 - b. Payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of ~~individual~~ health care practitioners on the use of a medical device if

- j. The provision of charitable donations provided that the donation:
 1. is not provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices, and
 2. does not otherwise violate the provisions of 105 C.M.R. 970.000.

970.009 Disclosure of Payments

1. Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical or medical device manufacturing company that employs or contracts with a person to sell or market a drug, medicine, chemical, device or appliance pharmaceutical or medical device manufacturer agent in the commonwealth shall disclose to the Department the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.
2. Each annual disclosure report shall be accompanied by a fee of \$2,000. The first annual payment of \$2,000 shall be due to the Department on July 1, 2009.
3. Disclosures shall be made for the previous calendar year using a standardized reporting format developed by the Department. The first required disclosure report shall cover the period from July 1, 2009 through December 31, 2009. Each annual disclosure report may be submitted to the Department electronically.
4. Pharmaceutical or medical device manufacturing companies shall certify that to the best of the best of the reporter's company's knowledge, information and belief, the report is true and accurate.
5. For the purposes of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not knowingly structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements of M.G.L. c. 111N, §6 and 105 C.M.R. 970.009.

970.010 Penalties

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1. A person who knowingly and willfully violates 105 CMR 970.000 shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event.

~~Every pharmaceutical or medical device manufacturing company, marketer or agent, and every other person subject to these regulations, is under an ongoing duty of good faith compliance.~~

- ~~2.~~ ~~3.~~ No pharmaceutical or medical device manufacturing company, or other person or employer shall discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse personnel action against any employee, applicant, health care practitioner or covered recipient because such employee, applicant, health care practitioner, or covered recipient takes or has taken any action in furtherance of the enforcement of 105 CMR 970.000.

970.011 Enforcement

1. Fines pursuant to 105 CMR 970.000 shall be issued by an authorized entity.
2. Ten days prior to the issuance of any fine pursuant to 105 C.M.R. 970.000, the authorized entity shall provide notice and an informal opportunity to dispute the issuance of the fine in person or by counsel or other representative as to the proposed action.
3. Notice shall be provided by mail, postage prepaid, to the person's usual place of business or, if unavailable, to the person's last known address.
4. A person aggrieved by the issuance of a fine by an authorized entity pursuant to 105 CMR 970.000 may seek judicial review in the Superior Court.
5. An authorized entity may file a civil complaint in Superior Court following the failure of any person to pay a fine issued by the authorized entity.