

**Joe McDermott**  
*Board of Health Chair*

401 Fifth Avenue  
Suite 1300  
Seattle, Washington  
98104

**Members:**

Sally Bagshaw  
David Baker  
Sally Clark  
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Shari Winstead

**Public Health Director:**

David Fleming, MD

**Administrator:**

Maria Wood

May 16, 2014

The attached correspondence was provided to Board of Health members after the date of the meeting on which R&R No, BOH14-02 concerning the fee schedule for the Secure Medicine Return program was voted upon.





Christine M. Simmon  
Senior Vice President  
Policy & Strategic Alliances

May 15, 2014

**VIA ELECTRONIC MAIL**

Councilmember Joe McDermott  
Chair, King County Board of Health  
516 Third Ave, Room 1200  
Seattle, WA 98104  
[joe.mcdermott@kingcounty.gov](mailto:joe.mcdermott@kingcounty.gov)

**RE: Proposed Fees for the Secure Medicine Return Regulations**

Dear Councilmember McDermott:

On behalf of the Generic Pharmaceutical Association (GPhA), thank you for your consideration of the following comments on the proposed fee schedule implementing a portion of the Secure Medicine Return Regulations.<sup>1</sup> GPhA is a non-profit association comprised of more than 65 manufacturers and distributors involved in the generic pharmaceutical industry. GPhA's members provide consumers world-wide with generic medications that are as safe and effective as their brand-name counterparts, but at a fraction of the cost. Generic drugs approved by the Food and Drug Administration have the same high quality, strength, purity and stability as brand-name drugs. GPhA's members are dedicated to providing safe, high quality, generic pharmaceutical products to the American public and believe first, and foremost, in protecting patient safety and ensuring access to affordable medicines.

Because many of GPhA's member companies are also covered producers under the Regulations, we welcome the opportunity to provide feedback on the proposed fee schedule.

**Proposed Fee Schedule Lacks Transparency**

In reviewing the proposed fee schedule, GPhA is concerned that no information is provided by the County as to how it arrived at the current structure and amounts. Both the Regulations and state law require the County to limit fees to the actual costs of plan review and program oversight with the currently proposed fee schedule,<sup>2</sup> yet there is no explanation as to the methodology employed by the County to determine the proposed fees. Because there has been no similar producer-funded program of this kind previously in operation in King County, there is no example to serve as a basis for comparison

<sup>1</sup> Board of Health Rule & Regulation 14-02.1.

<sup>2</sup> See Program Regulation Section 11.50.160(D) indicating that "[f]ees shall be calculated to recover actual costs"; and Wash. Rev. Code § 70.05.060(7) empowering the Board to "establish fee schedules for issuing or renewing licenses or permits for such other services as are authorized by law and the rules of the state board of health: PROVIDED That such fees for services shall not exceed the actual cost of providing such services."



to a new program. Therefore, as drafted, the current proposed fee schedule appears only to be an estimate.

As such, GPhA is concerned that any assumptions made by the County in formulating the fee schedule are not disclosed in the proposal. We respectfully request that the County provide additional detailed information regarding the analysis that went into calculating this fee schedule and the basis upon which the “actual costs” associated with review and oversight were drawn from. Moreover, we would ask that the County provide information regarding its process for refunding overages should any prepaid fees prove to be overestimated once they are reconciled.

### **Recommendations**

Without detailed analytics to further validate the County’s proposed fee schedule, GPhA believes that the County delay fee collection until after, at the earliest, the plan submission and review process. By collecting the fees following review, all parties will have had the benefit of seeing first-hand the actual time associated with the process; thus enabling an accurate accounting of fees.

In addition, GPhA recommends that the County establish a separate fund to hold any program fee overages that were paid but which cannot be specifically reconciled with any related task or County outlay. This fund could be reconciled on a program-year basis and overages could either be applied to a plan operator’s subsequent years’ fees, or, alternatively, refunded to the plan operator directly.

GPhA believes our recommendations will help align the proposal with the County’s obligations not to seek reimbursement for anything other than actual costs incurred from program review and oversight. To further this mutual goal, we would ask that the County not seek to charge any fees to any of our members or their designated plan operators until some process for validating actual fees incurred can be proposed.

GPhA would be happy to discuss this issue further with you or other members of the Board of Health and we look forward to your feedback.

Again, thank you for your consideration of our comments. Please contact me with any questions.

Regards,

Christine M. Simmon  
SVP, Policy & Strategic Alliances  
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May 15, 2014

VIA ELECTRONIC MAIL

Councilmember Joe McDermott  
Chair, King County Board of Health  
516 Third Ave, Room 1200  
Seattle, WA 98104  
[joe.mcdermott@kingcounty.gov](mailto:joe.mcdermott@kingcounty.gov)

RE: Proposed Fees for the Secure Medicine Return Regulations

Dear Councilmember McDermott:

Please accept the following comments on the proposed fee schedule implementing a portion of the Secure Medicine Return Regulations (Return Regulations).<sup>1</sup> BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. Many of BIO's member companies are covered producers under the Return Regulations.

BIO's initial comment relates to the overall approach the County is using to design and implement the proposed fee schedule. Notably, we are curious how the County is reconciling the proposed fee schedule with the County's obligation, under both the Return Regulations and state law, to limit fees to the actual costs of plan review and program oversight. Specifically, the Return Regulations permit the County to assess fees, with the requirement that "[f]ees shall be calculated to recover actual costs."<sup>2</sup> Further, the statute indicates that the Board may establish fee schedules, "PROVIDED that such fees for services shall not exceed the actual cost of providing such services."<sup>3</sup> Nonetheless, in the proposed fee schedule, the County does not provide any assessment or analysis of actual costs, nor any detailed support for the fees the County proposes to assess.

Therefore, we respectfully request that the County provide detailed information regarding the analysis that went into calculating this fee schedule, and the basis upon which the "actual costs" associated with review and oversight were drawn. Moreover, we request that the County provide information regarding its process for refunding overages should any prepaid fees exceed actual costs.

In the absence of such detailed analytics to further validate the County's proposed fee schedule, we would propose two related changes moving forward. First, we propose that the County wait at least until after the plan submission and review process before collecting any associated fees. By collecting the fees following review, all parties will have had the benefit of seeing first-hand the actual time associated with the process; thus enabling an accurate accounting of fees. Second, we propose that the County establish a separate fund

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<sup>1</sup> Board of Health Rule & Regulation 14-02.1.

<sup>2</sup> Program Regulation Section 11.50.160(D).

<sup>3</sup> Wash. Rev. Code § 70.05.060(7).



to hold any program fee overages that were paid but which cannot be specifically reconciled with any related task or County outlay. This fund could be reconciled on a program-year basis and overages could either be applied to a plan operator's subsequent years' fees, or, alternatively, refunded to the plan operator directly.

Absent the above-described changes to the County proposal, we do not see how the County will be able to ensure that its proposed fees are calculated to recover actual costs, as required under state law and County regulation. With this fundamental concern in mind, we would ask that the County not seek to charge any fees producers or their designated plan operators until such time as a process for validating actual fees incurred can be proposed.

We would be happy to discuss this issue further with you or other members of the Board of Health further.

If you should have any questions, or if we can be of any assistance, please do not hesitate to contact me.

Regards,

/S/  
Jeffrey Peters  
Deputy General Counsel, Health  
Biotechnology Industry Organization (BIO)



**JOHN A. MURPHY III**  
Assistant General Counsel

May 15, 2014

**VIA ELECTRONIC MAIL**

Councilmember Joe McDermott  
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[joe.mcdermott@kingcounty.gov](mailto:joe.mcdermott@kingcounty.gov)

**RE: Proposed Fees for the Secure Medicine Return Regulations**

Dear Councilmember McDermott:

Please accept the following comments on the proposed fee schedule implementing a portion of the Secure Medicine Return Regulations.<sup>1</sup> The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association that represents the country’s leading biopharmaceutical research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Additionally, as it pertains more specifically to this comment letter, many of PhRMA’s member companies are also covered producers under the Regulations.

Our initial and most substantive comment relates to the overall approach the County is using to design and implement the proposed fee schedule. Notably, we are curious how the County is reconciling its obligation under both the Regulations themselves as well as under state law to limit fees to the actual costs of plan review and program oversight with the currently proposed fee schedule.<sup>2</sup> Specifically, the currently proposed fee schedule appears only to be an estimate since no plans have actually been submitted nor has a similar producer-funded program of this kind previously been operated in King County from which to draw upon for comparative purposes. At a minimum, we respectfully request that the County provide additional detailed information regarding the analysis that went into calculating this fee schedule and the basis upon which the “actual costs” associated with review and oversight were drawn from. Moreover, we would ask that the County provide information regarding its process for refunding overages should any prepaid fees prove to be overestimated once they are reconciled.

In the absence of such detailed analytics to further validate the County’s proposed fee schedule, we would propose two, related, changes moving forward. First, we propose that the County wait until after, at the earliest, the plan submission and review process before collecting any associated fees. By collecting the fees following review, all parties will have had the benefit of seeing first-hand the actual time associated with the process, thus enabling an accurate accounting of fees. Second, we propose that the County establish a separate fund to hold any program fee overages that were paid but which cannot be

<sup>1</sup> Board of Health Rule & Regulation 14-02.1.

<sup>2</sup> See Program Regulation Section 11.50.160(D) indicating that “[f]ees shall be calculated to recover actual costs”; and Wash. Rev. Code § 70.05.060(7) empowering the Board to “establish fee schedules for issuing or renewing licenses or permits for such other services as are authorized by law and the rules of the state board of health: PROVIDED That such fees for services shall not exceed the actual cost of providing such services.”

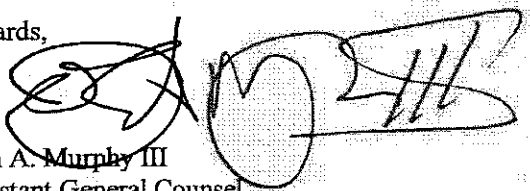
specifically reconciled with any related task or County outlay. This fund could be reconciled on a program-year basis and overages could either be applied to a plan operator's subsequent years' fees, or, alternatively, refunded to the plan operator directly.

Absent the above-described changes in the fee schedule methodology and collection proposal, we do not see how it can be accurately or transparently reconciled with the County's obligations not to seek reimbursement for anything other than actual costs incurred from program review and oversight. With this fundamental concern in mind, we would ask that the County not seek to charge fees to any of our members or their designated plan operators until some process for validating actual fees incurred can be proposed.

We would be happy to discuss this issue further with you or other members of the Board of Health and we look forward to hearing your comments on our suggested changes.

In the meantime, if you should have any questions please do not hesitate to contact me.

Regards,



John A. Murphy III  
Assistant General Counsel  
PhRMA

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