

# mHealth Regulatory Coalition

## Washington, DC

{Insert Date}

[COMPANY NAME  
ADDRESS, ETC.]

RE: mHealth Regulatory Coalition

We are pleased to have the opportunity to serve you as a member of the mHealth Regulatory Coalition (“Coalition”), and we look forward to working with you to achieve the Coalition's goals. The purpose of this letter is two-fold: (1) to outline the basic goals, structure and dues of the Coalition; and (2) to address the relationship between the Coalition and Epstein, Becker & Green, P.C. (“EBG”). We hope you find this information helpful, and we look forward to your active participation in the Coalition.

### **MISSION**

The goal of the mHealth Regulatory Coalition is to work with the U.S. Food & Drug Administration (“FDA”) to write a guidance document that addresses what the Agency regulates and what it does not. This Coalition will be temporary, existing just long enough to accomplish the purpose of drafting the proposed guidance document. Estimated time for completing the process is one year.

### **PRINCIPLES AND FEES**

Below follows a summary of the relevant characteristics of the Coalition:

1. Nature of the Coalition. This coalition will be temporary, existing just long enough to accomplish the purpose of drafting the proposed guidance document. Estimated time for completing the process is one year.
2. Member control. The decisions and activities of the Coalition will be controlled by the members of the Coalition. No policy decisions will be made or activities undertaken without agreement of the Coalition. In most cases, we will operate by consensus on policy positions and activities to be undertaken by the Coalition. In any instance in which a vote is required, decision-making will be by 80% rule of all member institutions -- both association and company.
3. Meetings. The Coalition typically will meet by teleconference to discuss issues and business pending before it. When appropriate, the Coalition may meet in person at a convenient location. Every effort will be made to schedule meetings during times when the majority of Coalition members are available to participate. Notice of teleconferences and in-person meetings typically will be provided by e-mail. Between such teleconferences and meetings, the Coalition will conduct its business through e-mail and oral communications, unless the Coalition agrees otherwise.
4. Coordination by EBG. Brad Thompson will be the principal member of EBG responsible for coordinating all EBG services involved in representing the Coalition, including all communications

with you and other members of the Coalition. Please bring to my immediate attention any issues related to billing or services provided, so that such matters can be resolved promptly.

7. Budgets and Fees. Each member company will be billed monthly for its share of the costs. In addition to fees, member companies may be responsible to pay for their share of disbursements and certain other expenses incurred in support of the Coalition; those expenses will be charged equally to Coalition members. Payments are due upon receipt of our invoice, and will be considered past due 30 days after receipt.
8. Leaving the Coalition. If at any point your company decides to leave the Coalition, simply let me know. Your company will not be billed for the following month, forward.

#### **RELATIONSHIP BETWEEN THE COALITION AND EBG**

EBG will provide legal representation for the activities of the Coalition and will also assist in facilitating and managing the Coalition's activities. In addition, as counsel to the Coalition, EBG will provide advice and counsel regarding regulatory policies affecting combination products. We will work closely with Coalition members to facilitate preparation of policy positions and documents for submission to the FDA. We will look to the Coalition for our instructions, and recognize that the scope of our services to the Coalition may change, as directed by the Coalition. In the event that the activities of the Coalition meet the definition of "lobbying", EBG will rely on an affiliate, National Health Advisors, LLC, which is a registered lobbyist.

EBG also offers non-legal, expert consulting services in such areas as regulatory affairs and reimbursement affairs. EBG does this through its affiliate, EBG Advisors, Inc., and, in some cases, by separate legal entities, such as The Anson Group. We may ask EBG to utilize these expert consultants to help us advise you, or you might wish to obtain their help directly.

As counsel to the Coalition, EBG is committed to maintaining the confidentiality of the information the Coalition entrusts to us. As lawyers, it is our ethical duty. It is also a principle of client service that is of paramount importance to us. Both EBG Advisors and The Anson Group are contractually bound to protect the confidentiality of information that the Coalition entrusts to us. For the attorney-client privilege to extend to communications involving consultants, the communication must be for the purpose of aiding us in providing legal advice. Therefore, if they are not assisting EBG in rendering a legal opinion of the law firm, the attorney-client privilege does not apply to communications involving EBG Advisors or The Anson Group. In those instances, we rely on contractual commitments for confidentiality.

EBG recognizes its professional obligation not to disclose confidential information or to use it for another party's benefit. Provided EBG acts in this manner, the Coalition would not for itself or any other party assert that EBG's possession of such information, even though it may relate to a matter for which EBG is representing another client, is a basis for disqualifying EBG from representing another client of EBG in any matter vis-à-vis the Coalition or any other party.

It is also important to understand that, simply by representing the Coalition, we do not also separately represent individual Coalition member companies or their affiliates, subsidiaries, or other constituents, nor do we separately represent their employees, officers, owners, or other persons related to Coalition member companies. If Coalition members would like to engage us to assist them in company specific matters that do not conflict with the representation of the Coalition, we do accept such separate engagements. In the absence of such a separate engagement, we reserve the right to accept engagements

form other Coalitions that under the rules of ethics would make us adverse to individual members of the Coalition.

In the event any dispute arises in connection with this engagement agreement, it is our desire to resolve it through amicable discussion. In the event that such discussion does not solve the problem, we believe that it is in the interest of both the Coalition and EBG that such a dispute be resolved through binding arbitration, rather than in a court.

Lastly, we would note that to the extent the Coalition requires competitive information from its members, each member should consider seeking separate legal advice regarding the antitrust implications of sharing such data.

If you find the foregoing to be acceptable, please indicate your company's agreement by signing the enclosed original of this letter agreement in your capacity as an authorized representative of your company and returning it to me at your earliest convenience. Please contact me if any of the above is unclear. Alternatively or additionally, you might wish to consult with your business advisor, accountant, or other professional advisors regarding the terms of this letter agreement.

This letter agreement will take effect when you execute and return this letter agreement. However, the effective date of this letter agreement will be retroactive to the date EBG first performed services for or on behalf of the Coalition. The date at the beginning of this letter agreement is for reference only. Even if this letter agreement does not take effect, the Coalition will be obligated to pay EBG for the reasonable value of any services EBG may have rendered to or on behalf of the Coalition. In such event, EBG reserves the right to assert that the reasonable value of its services is higher than the rate provided by this letter agreement as a courtesy to Coalition.

If you have any questions or concerns with the above terms, please let me know. We appreciate this opportunity to serve you and look forward to your involvement in the Coalition. Please e-mail a signed copy of this letter to me at your earliest convenience.

Sincerely,

**mHealth Regulatory Coalition**

A handwritten signature in blue ink, appearing to read "Bradley Merrill Thompson".

Bradley Merrill Thompson

Signed and accepted this day of \_\_\_\_\_, \_\_\_\_\_, 2010

[INSERT COMPANY NAME]

By \_\_\_\_\_