



July 6, 2018

**Via Electronic Submission to www.regulations.gov
(Docket No. HHS-OS-2018-0011)**

The Honorable Eric Hargan
Deputy Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Workgroup makeup, member selection, and meeting structure

Thank you for requesting comment on the Department of Health & Human Services' effort to create opportunities for the facilitation of public-private dialogue to increase innovation and investment in the healthcare sector. Medical Alley Association is uniquely positioned to assist in this effort, as our membership spans all stages of the innovation lifecycle and sectors of the healthcare industry. We champion and facilitate an environment that enables health technology and care organizations to innovate, succeed, and influence the evolution of healthcare.

The Department requested comments on improving communication and understanding between itself and those innovating and investing in the healthcare industry. Specifically, the Department asked for comments on how a workgroup to facilitate this goal should be convened and structured. The makeup of the workgroup, the selection of its members, and how its meetings are structured are each important to achieving the Department's goals of exchanging ideas on how to increase innovation and investment in the healthcare sector.

Makeup of the workgroup

The healthcare industry is rapidly changing and the workgroup membership should reflect this. A variety of representatives from the ecosystem of today – and the future – is necessary to properly evaluate the issues and challenges facing health innovation and investment. Members need to include those who can actually speak to the impact of laws and government regulations on the innovation curve – both helpful and harmful. Including members from all lifecycles of innovation, traditional and new sectors of the healthcare industry, and from a diversity of geographic locations (the "Categories") will ensure success of the Department's goals for the workgroup.

The workgroup should include members from all stages of the lifecycle of innovation. Ensuring perspectives from angel investors and private equity or venture capital firms are as important as including incubators and accelerators. Early-stage companies will bring different viewpoints and opinions from mature companies; multinational corporations bring yet another lens on what will drive increased investment in innovation within the United States rather than outside its borders.

Having the voices of the traditional sectors of the healthcare industry is necessary. These include payers, providers, and manufacturers. However, emerging industries such as digital health, regenerative

medicine, and personalized medicine should also be involved. New, larger players – from other technological spaces – just entering into healthcare also need to be included.

Ensuring a diversity of geography among the members is also important. What is needed to unlock innovation and investment in one region may not be the same as another. Understanding the challenges facing innovators throughout the country is important to continue to drive their work, increase their access to capital, and in doing so, improve health outcomes for Americans no matter where they live.

Workgroup size and selection of its members

Bringing together all these voices in a manner to produce positive outcomes requires a workgroup of a manageable size, while still preserving the needed diversity of viewpoints.

Several of the criteria mentioned in the above section could be satisfied by a single member, but that may not achieve the best result. For example, an early-stage digital health company based in Minnesota may check three boxes – but asking them to represent all three perspectives at once would be challenging. Similarly, a mature, publicly traded, medical device company in California is unlikely to have the same perspective as a similarly situated – but venture capital funded – company located in Texas, or a biotechnology incubator based just a few miles down the road.

To ensure proper representation of each Category listed in the previous section, we suggest that the workgroup be made up of 24 members – with eight designated from each of the Categories. This will allow for some overlap and still ensures each Category has sufficient representation on the workgroup. This also enables flexibility of membership – for example, members of the investment industry easily fit into two of the Categories – while not compromising the overall makeup.

Many geographic locations will be more heavily represented than others. That is how the health innovation and investment industries have grown and matured. An effort, however, to ensure that several areas of the country are included will lend more credibility to, and acceptance of, the work being done by the workgroup. Further, it is very important to not over-represent one particular part of the innovation lifecycle relative to another. As an example, having voices that understand investing in the health innovation industry is important, but a shortage of perspective from those seeking investment will result in missing other, more critical obstacles.

Selecting members will not be an easy task. The Department should rely on the expertise of those already working with those who are innovating and investing in the healthcare industry for member suggestions. Many states have organizations – such as Medical Alley Association in Minnesota – working to benefit the health innovation, health technology, or biotechnology industries in their respective states. The Department should reach out to these organizations and request submissions of potential members. The Department can then weigh those submissions, along with where the health innovation and investment clusters are located, and make determinations on who to include.

Structure of Meetings

The structure of the meetings needs to be focused. There should be a clear articulation of the particular problem that the group is attempting to solve. Manageable – and tangible – outcomes and outputs are necessary. A failure to clearly define what the group is working on and what it is attempting to accomplish will result in a lot of talking but little meaningful action.

Initial one-on-one or small group meetings should be held between workgroup members and the Department to determine what broad themes should be addressed. The Department should then again hold smaller meetings to narrow the scope even further. From there, small, manageable agendas can be put together with a select number of topics for each meeting are identified for the larger workgroup's consideration.

The Department could ask for written comments and ideas from each of the workgroup's members to facilitate discussion with Department leadership. Then, at the larger workgroup meeting, Department leadership can lead a discussion on how to proceed, based on member feedback and their own thoughts and perspective. This would enable each workgroup member to share their larger perspective while allowing the conversation to be focused on the best points for discussion.

We again appreciate the opportunity to comment and look forward to continuing to work with the Department on this exciting endeavor.

Thank you for your time and consideration.

A handwritten signature in blue ink, appearing to read 'Shaye Mandle', is positioned above the typed name.

Shaye Mandle
President & CEO
Medical Alley Association