

MedBiquitous Business Case/Working Group Charter – Disclosure of Financial and Non-Financial Interests

Please complete this form in its entirety. The first four sections (Mission, Context, Goals, Environmental Scan) must be completed prior to the start of the project. The remaining sections can contain preliminary answers but must be updated during the course of the project.

The questions in each section are meant to serve as prompts. Answering them directly is not required.

Working Group Charter

Mission

The relationships between health professions educators, researchers, and industry are complex. Collaboration with industry is often essential for bringing new treatments and devices to the healthcare marketplace in a scalable fashion. In some cases, financial ties and other commitments or relationships can unduly influence the content of education, published research, or care delivery. To address this concern, journals, continuing education providers, schools, societies, teaching hospitals and government agencies often require that authors and faculty disclose their financial interests and other relevant commitments or relationships. Many then work to manage any conflicts. Active researchers and faculty members find themselves spending large amounts of time completing duplicative disclosure statements for the various organizations with which they work, taking time away from their research and education activities. In some cases, organizations define terms differently, making reporting more complicated.

Context

In 2009 the Institute of Medicine (IOM) Committee on Conflict of Interest in Medical Research, Education, and Practice published a report calling for a more effective, centralized system for reporting financial interests. To date, this report has been cited 640 times.

The Physician Payments Sunshine Act, one aspect of the Affordable Care Act (2010) started data collection in 2013, with the final rule issued in 2018. Under the Physician Payments Sunshine Act, drug and device manufacturers and group purchasing organizations will report to the Centers for Medicare and Medicaid Services (CMS) payments made to physicians and teaching hospitals, and the data will be posted on a public website. CMS has developed a portal called Open Payments to share this data with the public. From their website, “CMS does not comment on what relationships may be beneficial or potential conflicts of interest. CMS publishes the data attested to by reporting entities. The data is open to individual interpretation.”

The Association of American Medical Colleges has developed a harmonized central system, Convey, that provides a single mechanism for individuals to input, update, and disclose information to requesting organizations. The platform integrates with existing institutional systems and all field elements will be accommodated and information provided to entities based on their own individual requirements.

Goals

Institutions could streamline the reporting of all interest disclosure requirements by using a centralized system for collecting data on financial and non-financial interests. This would eliminate duplicative work on disclosure forms. A technology standard for financial interest and disclosure reporting is essential to enable sharing of this data and relieve clinicians and researchers of the administrative burden of sending duplicative data to the organizations that require this data. Such a system could also improve the

accuracy and clarity of information reported by ensuring the consistency of data definitions used among organizations.

Scope

The following represents the current set of revisions being requested of this working group:

From the American College of Physicians:

The request has been presented to review the “Other” field as it is currently listed as a subcategory of “Independent Contractor”. The rationale from the organization is stated as follows.

The issue is the “Other” is currently listed as a subcategory of “Independent Contractor.” Our committee members render “professional service” for our organization and do not receive any financial compensation, it is strictly volunteer. While our Board members are fiduciaries of the organization, our committee members are not. Therefore, the only option they can choose is the “Other” under “Independent Contractor.” However, federal employees are barred from being “independent contractors” and therefore refuse to complete this. What we need is just a true “Other” category that is on its own rather than as a subcategory of independent contractor.

However, I would think that volunteer committee service would be common among all professional societies who would use this system, as well as other entities, and thus note that there is no option other than an “other” that is currently listed and could be chosen instead of that. The other thing that isn’t listed is an authorship. We need to know if someone has published an article on a topic that, for example, our clinical guidelines committee may be considering developing guidelines on. Again, there is no appropriate role for this within the company/organization that is specified, and the Intellectual Property is a little off the mark in that you would have to select “Other Intellectual Property” and it really provides financial options which are not applicable to authorships.

The ask is not to add a new field but rather to relabel the “Independent Contractor” to enable federal employees to complete their disclosures.

From University of Wisconsin-Madison:

The request has been presented to add an additional sub-field within those interest types where “Compensation” is collected. In the instance the discloser selects “paid” as the compensation type, the organization needs to not only know the total value but the “Hourly Rate” for the engagement to assess fair market value. Currently only the total value is being collected for compensation. The request is to add “Hourly Rate” as a sub-field.

Standards Environmental Scan

At present the author of this proposal does not know of any direct conflicts with existing standards development efforts. It is not known at this time what standards, if any, CMS Open Payments utilizes for data collection and sharing.

Work Plan

Please describe the anticipated timeline for this project and any anticipated resources needed by members of the working group.

This working group will be meeting monthly for approximately 6 months.

The following set of resources will be made available to MedBiquitous working groups.

- Workspace. (Exists on the Higher Logic virtual community platform provided by AAMC.) Conducting the day to day business of the working group will be done utilizing Workspace. The

platform allows for document sharing and curation, voting, task management and reporting. The platform will support our ANSI-compliant standards development process.

- Wiki. MedBiquitous Knowledgebase will serve as a public facing resource documenting the standards development process. All content published to this site will be curated by the working group leads and editors.
 - Microsoft Teams. Meetings of the working group supported by MedBiquitous Program Staff will be conducted utilizing Microsoft Teams.
 - SharePoint. Only on an as needed basis, access to MedBiquitous SharePoint will be granted for the creation of MS Word, Excel and PowerPoint documents. SharePoint will NOT be the primary resource for sharing official documents or storing research materials.
 - Literature Reviews. The AAMC Resource Center staff are available to assist with focused literature reviews.
 - Altova MissionKit (including XMLSpy). Any schemas that need to be documented with graphics or other processing can be done with this suite of tools. The MedBiquitous program staff have licenses for this use.
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The following sections should be updated during the standards development project, but attempts should be made to complete them during the initial submission of this form.

Business Case

Intended Outcomes

In what ways do you want health professions education and credentialing to be improved after this project?

What alternative solutions could emerge in parallel to what is being proposed/worked on?

What is the best option to pursue in support of the digital ecosystem of health professions education? (Documented as a work flow diagram)

What is the proposed technical solution? (Provide link to MedBiquitous Technical Use case document for this project)

How can we track the effectiveness of this standard, technical guideline or other work product of this project?

Implementation and Adoption Plan

Who is the target audience for this standard?

What materials need to be shared with them to help them understand the purpose of the standard and proper use?

Where/What are the channels for distribution?

When/What is the timeline for release to the public/market?

Validating Business Case

What issues can we anticipate?

What issues are already outstanding?

When are the milestones to determine the viability of the project output in the marketplace? (Must provide at least one check-in after 6 months of project development.)

What is the schedule for maintenance of the standard/technical guideline/other work product? (Required minimum: reaffirmation of an unrevised version every 5 years, with the initiation of the project for reaffirmation at least 15 months prior to the 5-year mark)