User Guide to the Template Agreement

Between a patient or patient advocacy organization and a pharmaceutical company

How to read this document:

- For the purpose of this document, we use the term “patients” in a broader sense for individual patients, caregivers, and patient organization representatives. You can find the definitions in the NHC Fair-Market Value Calculator Glossary of Terms.
- People, organizations, or companies that should compensate patients for engagement activities include biopharmaceutical, device, and diagnostic companies; academic researchers; patient-advocacy groups; policy makers; health care systems; and others who seek to engage patients as partners. Throughout this document, they are referred to as the “company” or “companies”.

Patient advocates and companies collaborate for many different reasons toward the goal of improving the patient centricity of medical products. When such collaborations take place, it is important that patients or patient organizations and the pharmaceutical companies involved clearly understand the work that will be undertaken. Patients/patient groups and companies must agree on expectations for deliverables, timelines, and fees and expenses, as well as other rights and obligations that each party will have. These expectations are typically laid out in contracts between the patients/patient groups and the companies. However, such contracts can be lengthy and hard to understand, and parties may not always have a good sense of what is “fair” when it comes to payment.

To make contracting easier for patients/patient groups and companies who work together, the National Health Council (NHC) has developed a patient engagement fair market value calculator that can help patient advocates and pharmaceutical companies determine appropriate payment arrangements. The NHC also has partnered with Patient Focused Medicines Development to publish contract templates that can be adapted for use in a variety of settings.

This document is a guide for using these resources.

Template Agreements between a patient or patient advocacy organization and a pharmaceutical company

The main objective of the contract/agreement template is to provide a starting document that patients/patient groups and companies can easily adapt for their use. The contract template should be modified as the parties to the arrangement see fit. The document includes template appendices for use in four common situations. However, the contract can easily be adapted for use in other settings by revising one of the template appendices. Example situations addressed in the template agreement include:

1. **Advisory Boards**: Pharmaceutical companies (or other companies) frequently form advisory boards to gain insight from various types of experts, including patients, caregivers, and patient group staff. They can provide important insight into the condition, clinically meaningful outcomes, perspectives on benefit-risk, and other topics. This insight may inform activities undertaken by pharmaceutical companies, including management of their current product pipeline and development of new therapies or treatments.

2. **Speaking Engagements:** Patients and patient group staff may participate as speakers at public events organized by pharmaceutical companies and others, such as conferences and workshops, as well as at semi-private or private meetings. They may be invited to speak on specific topics or have the opportunity to propose and develop their own content.

3. **Consulting Engagements:** Pharmaceutical companies may engage patients and patients/patient group staff as consultants on a short-term or longer-term basis, for focused input, ongoing advice, or creation of specific materials. They may be asked to help with specific projects or to participate in a number of different activities.

4. **Collaborations:** When it is clear that they have common interests and that both the patients and patient group staff and the pharmaceutical company(ies) would benefit from working together to pursue these interests, they may form collaborations. These can be short-term or long-term arrangements and typically involve multiple individuals from both organizations who cooperate to produce some sort of work product.

This template agreement addresses topics that are common to such agreements, including:

- **Information about the Parties Involved and Their Goals**
  Information about each of the parties (individuals or organizations) involved in the contract is typically included at the beginning of the document, often with some information under the heading "Whereas," which just means that the agreement will take the information included in that section into account.

- **Services**
  Ensures that everyone is on the same page about the work to be done, and what will result from that work.

- **Fees and Expenses**
  Makes clear what payment will be provided for work done and what expenses will be covered.

- **Independence and Conflicts of Interest**
  Recognizes the independence of the advocate(s), and is intended to preempt conflicts of interest, which arise when a person or organization has competing loyalties or interests.

- **Term and Termination**
  Sets forth expectations for when work will begin, how long it will last, and addresses how the end of the contract may be handled.

- **Confidentiality**
  Lays out expectations for what information will be considered confidential, and expectations for maintaining the confidentiality of that information.

- **Documentation of Meetings**
  Addresses rules about recording meetings, or information from meetings, so that all parties are aligned about if, when, and how meetings can be documented.

- **Intellectual Property Rights**
  Explains who owns material that may be used or created as part the work that is done.

- **Liability**
  Addresses responsibilities in the event that something goes wrong, including whether the patients can be held responsible and what the costs to the patient could be.

- **Data Privacy**
  Helps to ensure the protection of personal data used or collected as part of the work that is done; while the definition of personal data varies by region, it generally includes information related to an identified or identifiable person, such as date of birth, address, identifiable health information, etc.

- **Anti-bribery Compliance**
  Sets expectations that both parties comply with anti-bribery and anti-corruption laws and regulations.

Addressing these topics in a contract not only helps ensure that all parties to the agreement are on the same page, but also helps to protect the parties in the event that an issue arises after work has begun.

Instructions for Adapting the Template Agreement

To adapt the template for use in a specific setting:

1. Select the relevant version of Appendix 1 (which describes the type of arrangement) – or adapt one of those versions to fit your specific situation. Remember to remove the other versions that are not relevant.

2. Add details on the work that is envisioned to Appendix 1.

3. Carefully review the other sections of the template, including the main text of the agreement and the other Appendices, and update them as needed to ensure that they appropriately reflect each party’s responsibilities and expectations.

Things to Know about Negotiating Agreements

While finalizing the agreement may take a few rounds of drafting, review, and revision, having this template should streamline the process for both parties. During the negotiation process, both parties may have changes that they want to make to the agreement to ensure that it meets their needs. For example, a company may have standard language that it likes to include in all contracts and may request that certain sections of the contract be updated to include that language. Similarly, an individual patient or patient group may want to expand certain sections of the agreement to ensure protection of their own rights and limit their liability. To simplify the negotiation process and make sure that changes to the contract are clear, it can be helpful to use a "track changes" or "red-lined version" to transparently show all revisions and set up telephone/video calls (e.g. Zoom) to talk through sections of the contract that may include more substantial revisions.

Fair-Market-Value Calculator

The purpose of the NHC patient engagement fair-market-value (FMV) calculator is to help patients/patient-group staff and companies determine appropriate compensation payment rates for partnerships, accounting for professional fees (i.e., speaker or consulting fees) and separately, reimbursement for expenses incurred in connection with the arrangement. The calculator considers factors such as the type of participant, expertise required, time required, how participants will interact, expenses, and other factors that may inform payment. Instructions for using the calculator as well as the methodology for creating the calculator are available with the NHC FMV calculator.