

The National Health Council

Principles for Compensating Patients for Patient Engagement Activities

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NATIONAL HEALTH COUNCIL

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National Health Council • 1730 M Street NW, Suite 500, Washington, DC 20036-4561 • 202-785-3910

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Background

Like other types of consultants, patients should be compensated for their time and contributions. This document is intended to provide general guidance regarding compensating patient-community representatives for their time and expertise when participating in patient engagement activities. It also includes principles related to reimbursement for related out-of-pocket costs such as travel. The principles listed here are general and not intended to be prescriptive. They should be adapted as required by individual circumstances. There can always be exceptions-to-the-rule as patient engagement is an evolving science.

Participants in engagement activities eligible for compensation include: a patient with one or more medical conditions; a person with specific risks for a condition; an unpaid/non-professional caregiver (i.e., not a paid aide); family members who may or may not also be caregivers; or a patient organization's staff member. Unless noted otherwise, this group of potential participants are collectively referred to as "patients" or "participants" throughout the remainder of this document.

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 "payer" or "compensator."

Patients understand that compensation for their time and/or expense reimbursements is not intended to influence any purchasing or referrals of products or services. Agreements with patients and/or patient groups should clearly distinguish between research activities and product-specific promotional activities (which should not be considered patient engagement). These Compensation Principles are intended to apply to meaningful engagement activities in research, education, and awareness, and are not intended to apply, though most may, to marketing activities or market research, which would more typically might involve specific product mentions.

The patient engagement activities referred to in this document are specifically directed at those related to medical-product development. Activities related to patients being engaged in their own health care are not the specific focus of these principles. However, the principles may be applicable to other relevant circumstances where patient input is desired.

The Principles are divided into these topic areas:

- Type of Patient Engagement Participant
- General Compensation
- Administrative/Logistics
- Time Commitment
- Travel and Reimbursement Considerations
- Declining Compensation
- Other Considerations

Type of Patient Engagement Participant

Payer/Compensator:

- Companies should explore and value diverse backgrounds when engaging patients and caregivers. Engage patient partners whose expertise is based on lived experience with relevant diseases, conditions, interventions (treatment and others), and/or relationships with their communities. Companies should also include patients and families who may have to participate remotely due to the nature of their specific condition or conditions.
- The required expertise of the patient participant should be in alignment with the activity they will take part in. The participants may have various kinds of expertise, including but not limited to: experience living with or being at risk for the condition; experience making treatment decisions about the condition; general knowledge about the condition beyond individual experiences extending to the population or subpopulations with the condition; subject-matter knowledge such as clinical trials, epidemiology, or regulatory matters; knowledge regarding a patient advocacy group or community activities, policies, or data; and/or communication/speaking experience and training.
- Companies sometimes contract with well-known patients (can be referred to as a “celebrity” patient – e.g., individuals who are entertainers and also diagnosed with a disease) who often have an established contractual rate for speaking and other efforts. Typically, contracts with celebrity patients are not for routine patient engagement activities, but instead are for branded/disease marketing activities. Thus, contracts with these patients are outside the scope of these patient-compensation principles. Companies should have separate policies in place for compensating celebrity patients. Engagement with a celebrity patient should not be assumed to be a meaningful patient engagement activity.
- If companies are contracting with a patient-advocate staff member who works for a patient group, they should compensate the patient group rather than the individual staff member (especially if the person is providing the same expertise that they would have working as a patient-group representative). Patient groups

should consider implementing conflict-of-interest policies that specify if and when their employees can receive payment individually for work done for other organizations. This is in accordance with the spirit of the NHC's [Standards of Excellence](#), specifically standards 10, 24, and 30.

General Compensation Principles

Payer/Compensator:

- Payments should be at fair-market value and for legitimate, reasonable, and necessary services. Compensation policies should reflect that the compensating organization recognizes and values the time, experiences, energy, skills, knowledge, networks, etc. that the patient offers to the activity or audience (for more information on specific hourly rates, please see the NHC Fair-Market Value Calculator [here](#)).
- There should be no large discrepancies, especially for any one activity, for compensation for individuals doing the same work requiring the same expertise within the same organization.
- Virtual engagement should be compensated at a comparable rate to in-person engagement.
- Compensation rates should be negotiable within a range of fair-market value, similar to staff, consultant, or freelance fees.
- Many individuals cannot afford to take time off from work/daily duties without compensation. If engagement were to only include those patients who can afford to volunteer their time, those volunteers likely represent a small part of the entire population with that particular disease or condition. Therefore, fair compensation for engagement activities can help improve representativeness by expanding the population of patients that can participate.

Patient/Participant

- Patient partners should be aware they have the right to express concern if they believe the payment offered for their participation is insufficient.
- Individuals and patient groups should be aware that there may be tax or tax status implications or liabilities when receiving compensation for an activity. While it is not the responsibility of the compensation payer to provide tax or legal advice, the compensator may want to suggest the patient or patient group seek tax or legal advice before entering into agreements to avoid unintended/unanticipated tax liability or tax status issues. The compensator should inform the patient if they will receive a 1099 form as a result of the compensation.

Administrative/Logistical Principles

Payer/Compensator:

- If internal policies regarding compensation do not yet exist, payers should consider co-creating guidelines with patient partners.
- Discussion of compensation and options should be in private with individual patients prior to the start of the project. This encourages the patients to make specific need or accommodation requests without fear of judgement.
- A written agreement between the patient and payer should be developed outlining terms, responsibilities, time frame, expectations, etc. prior to the start of the activity. It should be written in clear and easy to understand language.
- Patients should be clearly informed of how and when the compensation and/or reimbursements will be administered and if any conditions are attached (or documentation required).
- The payer should ensure the patient knows who is to be contacted if any questions or concerns arise regarding compensation or reimbursement.

Time Commitment

Payer/Compensator:

- Whether compensation for an activity is paid on an hourly basis or an activity basis, the compensation calculation should consider the total time commitment of the patient.
- Time commitment should include the initial training required for the specific activity, preparation, meetings (including planning and review meetings), follow-up for project deliverables, and other post-activity engagement.
- The patient should be compensated for travel time, including local or long-distance travel. Participant travel time may be compensated at the full hourly rate, some portion thereof, or based on distance traveled. Expenses incurred as a result of travel are discussed in the following section.

Travel and Reimbursement Considerations

Payer/Compensator:

- Reimbursement for travel or other expenses required to participate in a project should be viewed as separate and distinct from compensation, as the reimbursement represents expenses incurred by the patient that he/she would not otherwise incur.
- The payer should clearly lay out for the patient what is reimbursable in advance. Descriptions for expenses should be included (e.g., reasonable and customary, or coach class airfare), or if the payer has limits to expenses (e.g., per diem rates).
- Examples of expenses that may be reimbursed include:
 - Transportation (e.g. train, mileage, airfare, Uber, taxi, or shuttle)

- Accommodations
 - Meals
 - Conference registration
 - Miscellaneous expenses such as hotel internet or parking.
- Examples of what is not included are also helpful, e.g., pet care.
 - Guidelines for out-of-pocket expenses covered, documentation required, and instructions for timeframe and how to submit for reimbursement should always be provided well in advance of travel and before travel is booked.
 - Whenever possible, the payer should pay for expenses directly (e.g., purchase the train or airline ticket) rather than the patient paying upfront and being reimbursed at a later time. This reduces financial stress for the patient partner.
 - Depending on a patient's circumstances, it may be appropriate to cover the travel of one adult care partner to accompany the patient.
 - Companies should take into account a patient's mobility limitations when arranging transportation (e.g. deciding on whether or not to hire a car service). Payers should work with the patient to identify additional expenses that may be medically necessary (e.g., rental scooter, rental oxygen, or certain seat assignments on a plane).

Payer/Compensator and Patients/Participants

- Limits may be placed on the amounts covered for travel expenses, especially if there's an understanding that the patient is not travelling solely to take part in one payer's activity (e.g., Patient is attending a conference for a variety of invited presentations and is also asked to participate in company-sponsored advisory board. In that case, expenses would be divided among multiple payers and not double payment/reimbursement).

Declining Compensation Principles

Payer/Compensator and Patients/Participants

- Patients can decline compensation and should know that working as a volunteer does not impact their ability to participate. In the event that participants decline monetary compensation, non-monetary forms of compensation may be offered (e.g., registration for a conference); however, companies should have clear policies on if/when this is allowable. It should be recognized that some government bodies might consider this taxable compensation.

Payer/Compensator

- Patients should be educated via a clear disclosure or other communication that accepting payment from a company could affect disability payments or other forms of government benefits. Patients should be made aware that accepting non-monetary compensation can still have tax implications.
- Patients should be made aware that accepting a payment from a company can result in a conflict-of-interest when the patient participates in other patient engagement activities with some government and other organizations.
- Donation of payment to third party organizations in lieu of direct compensation is discouraged. It is recommended that participants be compensated directly, and they can direct donations to third parties individually. Companies should apply their existing policies to determine whether or not they can accommodate requests for payment to go to a third party/charitable organization.

Other Considerations

Payer/Compensator

- A patient participant's independence might become questioned if, for example, a sizable portion of the individual's income is from one company. To avoid these instances, companies may establish aggregate-spend limits for individual patients (e.g., total compensation to a patient not to exceed a certain percentage of their total annual earning potential at their defined FMV rate). Companies may consider a cap in the future if data indicate it may be necessary. This is similar to the policies some organizations have for key opinion leaders and physicians.
- Patients should not be offered reduced-price goods or services that influence conversion from competitor products.
- Patients should not be asked to divulge personal medical information in order to participate in a program.
- Patients should be notified if the activity requires confidentiality.
- Patients should be notified who will be present and listening to/ have access to their private health information.

This set of Principles for Compensating Patients for Patient Engagement Activities was created as part of the National Health Council's toolkit to support sponsor-patient engagement. Other tools in this toolkit include:

- A Fair-Market Calculator,
- Templates for conflict of interest and privacy principles, and
- Templates for contracts with patients.

This toolkit is intended to ensure that patients and other stakeholders enter patient-friendly agreements as a part of medical-product development.

Other Budget Considerations

Payer/Compensator

The purpose of this toolkit is to ensure that patients and other stakeholders enter patient-friendly agreements as a part of medical-product development. The Fair-Market Value (FMV) Calculator was created to provide an estimated, reasonable, and fair hourly compensation range for a patient or patient-group staff member's time spent on a patient-engagement activity. It does not include other expenses associated with the patient engagement activity (e.g., travel, supplies, IRB fee) and is not intended to be used to assess the rate for access to research, data, or other-fee-for service applications as that will be case-specific.

Illustrative example: If a patient group is engaged to recruit patients (for a patient-engagement activity), the FMV calculator provides an estimated compensation range for the individual staff member's time recruiting patients. To complete the patient engagement activity, the staff member taps into a member database. The member database is an asset requiring annual investment on the part of the patient group, which is recouped through access fees. Thus, it is expected that a budget will include staff time estimated using the FMV calculator and database access fees.

The following documents were reviewed, and content was incorporated into the development of these principles:

- Genetic Alliance. A Guide to People-Centered Research: Considerations for Community Stakeholder Compensation. <http://geneticalliance.org/sites/default/files/Considerations%20for%20Community%20Stakeholder%20Compensation.pdf>
- Healthivibe, A Call to Action: Advancing the Conversation Around Fair Market Value of Compensation for Patient Insights Work. https://healthivibe.com/resource_files/Patient_Insights_FMV_ACalltoAction_27March2019_Final.pdf
- Richards, Dawn P.; Jordan, Isabel; Strain, Kimberly; and Press, Zal (2018) "Patient partner compensation in research and health care: the patient perspective on why and how," *Patient Experience Journal*: Vol. 5: Iss. 3, Article 2. DOI: 10.35680/2372-0247.1334 Available at: <https://pxjournal.org/journal/vol5/iss3/2>
- PCORI, Financial Compensation of Patients, Caregivers, and Patient/Caregiver Organizations Engages in PCORI-Funded Research as Engaged Research Partners. <https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf>
- The Change Foundation, Should Money Come into It? A Tool for Deciding Whether to Pay Patient-Engagement Participants. <https://www.changefoundation.ca/patient-compensation-report/>
- WECAN, PFMD Fair Market Value Survey. <https://wecanadvocate.eu/fmv-survey/>
- SPOR Networks in Chronic Diseases and the PICHI Network, Recommendations on Patient Engagement Compensation. https://diabetesaction.ca/wp-content/uploads/2018/07/TASK-FORCE-IN-PATIENT-ENGAGEMENT-COMPENSATION-REPORT_FINAL-1.pdf
- Myeloma Patients Europe, Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies. https://www.mpeurope.org/legal_agreements/wp-content/uploads/2019/03/Legal_Agreements_A5_3mm-bleed_PRINT_v2.pdf
- Canadian Institutes of Health Research, Considerations when paying patient partners in research. <http://www.cihr-irsc.gc.ca/e/51466.html>
- EphMRA, Code of Conduct. <https://www.ephmra.org/media/2278/ephmra-code-of-conduct-august-2018-gdpr-update-v5-for-issue.pdf>
- EFPIA, Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations. https://www.efpia.eu/media/24310/3c_efpia-code-of-practice-on-relationships-pharmapluspt-orgs.pdf
- FDA Office of Good Clinical Practice, Payment and Reimbursement of Research Subjects Information Sheet; updated Jan. 25, 2018.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

- Office of Inspector General, Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003, p. 21.
<https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>
- EUPATI, Guidance for patient involvement in industry-led medicines R&D.
https://www.eupati.eu/patient-involvement/guidance-for-patient-involvement-in-industry-led-medicines-rd/#Introduction_to_patient_involvement_in_industry-led_medicines_RD
- CTTI Recommendations: Effective Engagement with Patient Groups Around Clinical Trials. <https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf>
- DIA's Considerations Guide to Implementing Patient-Centric Initiatives in Health Care Product Development.
<http://engage.diaglobal.org/PatientEngagementConsiderationsGuide.html>
- IFPMA, Code of Practice. https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf
- IFPMA, Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry.
<https://www.ifpma.org/wp-content/uploads/2014/01/Consensus-Framework-FINAL.pdf>
- Witteman, H.O., et al., Twelve Lessons Learned for Effective Research Partnerships Between Patients, Caregivers, Clinicians, Academic Researchers, and Other Stakeholders. J Gen Intern Med, 2018. 33(4): p. 558-562
- U.S. Treasury Department, Internal Revenue Code, Section 1.170A-1(c)(2).
<https://www.irs.gov/pub/irs-drop/rr-03-28.pdf>.
- Boutin, M., Paying Patients for Their Expertise: What is Fair?, 2018.
<https://globalforum.diaglobal.org/issue/december-2018/paying-patients-for-their-expertise-what-is-fair/>