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Fair market value compensation for patient engagement

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"A growing body of evidence demonstrates that patients who are more actively involved in their health care experience better health outcomes and incur lower costs. As a result, many public and private health care organizations are employing strategies to better engage patients, such as educating them about their conditions and involving them more fully in making decisions about their [individual] care."[1] As part of this growing patient activation and involvement, patients and patient organizations are also becoming more and more involved in regulatory and financial processes such as product development, reimbursement decisions, and promotion of therapies. Becoming an active player in the healthcare market made both regulators, payers, and healthcare companies develop guidance on interacting with patients and patient organizations. The objective of this article is to explore payment considerations for these entities, including their fair market value (FMV).

Patient engagement

A patient organization is typically a nonprofit institution that primarily represents the interests and needs of patients, their families, or other caregivers. Biopharmaceutical companies and patient organizations enjoy productive collaborative relationships that benefit public health. Life sciences companies, including pharmaceutical companies, share many common interests with patient organizations, including, most importantly, a common commitment to patients and shared mission to discover cures and fight disease. In the mission of innovation and service to patients and caregivers, companies frequently work together with patient organizations to sponsor research, provide educational and support services for patients, and award grants to benefit the mission of patient groups. In order to help assure that relationships between biopharmaceutical companies and patient organizations remain true to their goal of advancing biomedical research, healthcare innovation, and access to patient care and services, such relationships should be structured to ensure the independence of the patient organization and appropriate support of the organization's mission.

In recent years, regulators and payers started engaging with patients as well. As an example, the Food and Drug Administration (FDA) Patient Representative Program "offers patients and caregivers the opportunity to provide critical advice to the agency as it regulates medical products—drugs, biologics, and devices."[2] "Patients and advocates are appointed as Special Government Employees (temporary employees) to provide direct input to agency staff as they share valuable insight on their experiences with various diseases, conditions, and devices while gaining access to confidential information....FDA Patient Representatives engage with scientific members and other experts as they participate on FDA Advisory Committees and panels and consult with agency's review divisions."

Furthermore, the FDA and the European Medicines Agency (EMA) have created a new work group on patient engagement called the FDA/EMA Patient Engagement Cluster.[3] "The cluster allows FDA and EMA to share best practices involving patients along drug and biologic regulatory lifecycles."

Patient compensation

Patients either acting as individuals or on behalf of a patient organization are often involved in participating in company-sponsored research and development of new therapies, ethics committees reviewing clinical trials, regulatory authorities reviewing medical data, and health technology assessment/reimbursement agencies deciding on healthcare coverage. It should be recognized that in many situations, patients involved in these activities do so voluntarily. However, in recent years, different stakeholders—including patients—raised the issue of patient compensation for the work and time dedicated to the above-mentioned activities.

From a compliance perspective, these collaborations must be ethical, transparent, and based on a legitimate need, ultimately driving better healthcare management and patient outcomes. The primary route for engagement with patients is through patient organizations. However, when permitted by federal laws and regulations, pharmaceutical companies and associations may engage with individual patient experts depending on the circumstances, type of service, experience, and expertise required.

All parties should be transparent about any compensation arrangements. At a minimum, a written agreement should have a clearly defined description of the activity and its objectives, the nature of the interaction during the activity, consent (if relevant), release, confidentiality, compensation, data privacy, compliance, declaration of conflict of interest, and timelines. Interaction may only proceed on the basis of a written agreement that, at a minimum, spells out the basic elements of the collaboration (e.g., rules of engagement, compliance, intellectual property, financial payments).

In general, consideration should be given to compensate for patients' total time invested plus expenses. Any compensation offered should be fair and appropriate for the type of engagement. In addition, one should cover the costs incurred by patient organizations when identifying or supporting patients for involvement in activities (i.e., peer support groups, training, and preparation). Such compensation may also include indirect in-kind benefits (e.g., a patient organization providing services free of charge) or any other nonfinancial in-kind benefits provided to the patient/patient organization (e.g., training sessions, website setup).

For example, the "FDA pays [patient representatives] a salary for the time spent during meeting and also covers expenses, such as flights, lodging and meals, if the meeting is more than 50 miles from the FDA Patient Representative's home."[4]

In Europe, the European Federation of Pharmaceutical Industries and Associations, which is a pharmaceutical industry association in consultation with patient organizations such as WECAN (Workgroup of European Cancer Patient Advocacy Networks) and Patient Focused Medicines Development coalition, published a white paper in June 2019 on patient remuneration, stating:[5]

> Appropriate and effective collaboration between Patients and the pharmaceutical industry has the potential to co-create and co-develop better health outcomes. This collaboration must be based on general principles applicable to any contracted services: identification of a legitimate need, definition of the service required, signature of a written agreement, reception of the deliverable, etc.

FMV considerations

Once it is widely accepted that patients are part of the stakeholders acting in the healthcare arena and are actively involved in different activities in the life cycle of new therapies, it becomes obvious that they should be compensated for their time and efforts.

As patient compensation became a norm, one should define how to establish payment mechanisms that assure payment is of fair market value and not excessive.

The European Federation of Pharmaceutical Industries and Associations' white paper on patient remuneration states that remuneration to patients "should be fair, reasonable, appropriate and should not exceed the fair market value of the services provided." While the level of remuneration, including its methodology, is an internal company decision, pharmaceutical companies should consider several factors to determine the appropriate remuneration, including:

- "Individual expertise of the Patient: level of experience, prior training, or experience relevant to the service provided, attendance at previous scientific meetings, transferable skills relevant to the engagement
- "Complexity of the tasks assigned, for example international vs national meetings
- "Total of time invested: including preparatory time, length of the engagement
- "Country of residence – taking national cost of living index (e.g. GDP level) into consideration"

In the US, the National Health Council has announced in early 2019 an initiative to develop tools to support sponsor–patient engagement.[6] The National Health Council wants to ensure that all stakeholders confidently enter into ongoing, compliant, and sustainable engagement efforts that effectively drive healthcare innovation based on patient and caregiver insights, which must be collected in a trusted and high-quality manner. This initiative includes the development of an FMV calculator[7] for compensation of patients involved in patient engagement activities in order to ensure uniformity.

One of the critical questions regarding FMV is tiering—it is widely accepted that healthcare professionals are compensated on a tier base depending on their seniority, publications, academic affiliation, etc. Some companies and research organizations suggested tiered payments based on the type of activity, such as survey participation, presentations in conferences or meetings, or participation in advisory boards and committees.

The European Patients' Academy[8] suggested a scale of patient expertise that might serve the tiering approach:

- "'Individual patients' with the disease in question, parents or carers of those patients, can provide valuable input to the patient information sheet and informed consent/assent form."
- "'Patient advocates' have an in-depth knowledge of living with the disease from their own experience and might have a level of understanding of research and medicines development for this disease."
- "'Patient organization representatives' are either patients with the disease in question and/or actively engaged in a relevant patient organization and are exposed to the disease experience of many individuals. They are knowledgeable about the needs, desires and opinions of this community and thus will be relatively representative."
- Patient experts (e.g., European Patients' Academy fellows) "have personal experience of living with the disease and/or the combined knowledge from working with members of their patient organization. In addition, they have a comprehensive understanding of all aspects of the medicines development process."

A survey conducted by WECAN in 2019 on FMV found that patients strongly agreed that the individual expertise, community insight, community leadership, complexity of tasks, and total time invested should increase FMV rate.[9] Factors for measuring individual expertise should include specifically advocacy track record, disease and

treatment knowledge, healthcare/research systems knowledge, personal experience, and completion of training programs.

However, when looking at the methods for deciding on basic compensation rates, there is no directly comparable benchmarking for patients. It has been suggested to benchmark compensation comparing to positions requiring similar experience, knowledge, and skills for the different patient engagement activities such as hospital patient representatives, research positions, health educators, etc.

Last, but not least, in many cases patients requested to enable the right to opt out from any financial compensation or to have the right of choice of compensation recipient such as a specific patient organization. This request can raise some concerns regarding transparency and potential hidden agendas and should be thoroughly discussed. Another issue that needs to be taken into consideration in this perspective is that patient compensation may affect patient taxation and/or disability payments.

Conclusion

As patients are becoming more active and influential in the healthcare system, their engagement justifies receiving compensation. However, from a compliance perspective, no clear rules or guidelines exist regarding the compensation of patients. General compensation rules for justifying the engagement, such as proof of service provided, transparency, and FMV payments, apply for patients as well. Several organizations in both the US and the EU are actively working on producing FMV guidelines for patient compensation, but no standard is available yet. Therefore, the issue of patient compensation poses significant risk for payers and should be closely monitored and scrutinized.

The opinions expressed in this article are the author's personal views and do not necessarily represent his workplace.

Takeaways

- Patients and patient organizations are becoming more involved in regulatory and financial processes such as product development and reimbursement decisions.
- Most fair market value compliance efforts focused on healthcare professionals and did not consider patient compensation.
- From a compliance perspective, patient engagements must be ethical, transparent, and based on a legitimate need, ultimately driving better healthcare management and patient outcomes.
- Individual expertise, disease insight, complexity of tasks, and total time invested are some of the major factors determining the fair market value compensation rate.
- Individual patient expertise should include specifically advocacy track record, disease and treatment knowledge, healthcare/research systems knowledge, personal experience, and completion of training programs.

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2 "About the FDA Patient Representative Program," Food and Drug Administration, May 3, 2018, https://bit.ly/3nlEAgb.
3 "FDA and European Medicines Agency Patient Engagement Cluster," Food and Drug Administration, January 8, 2018, https://bit.ly/3aeDU8G.
4 "FAQs About the FDA Patient Representative Program," Food and Drug Administration, June 20, 2019,

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8 Ingrid Klingmann et al., "EUPATI and Patients in Medicines Research and Development: Guidance for Patient Involvement in Ethical Review of Clinical Trials," *Frontiers of Medicine* 5 (September 2018), http://bit.ly/2IRnqIl.
9 Jan Geissler et al., "Compensation for patient experts at fair market value," WECAN, October 28, 2018, https://bit.ly/2KpwjJM.