ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Docket Number: FDA-2016-D-1307

Dear U.S. Food & Drug Administration (FDA):

ISPOR—The Professional Society for Health Economics and Outcomes Research - is pleased to respond on behalf of its membership to your consultation titled **"Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers – Guidance for Industry"**

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. ISPOR membership includes nearly 18,000 individual and chapter members from more than 100 countries worldwide. The number of individual members in the US exceeds 2,500. Our membership is uniquely diverse and represents a variety of stakeholder perspectives, including research organizations, academia, payers, patient groups, government, healthcare professionals, health technology assessment bodies, and the life sciences industry. ISPOR also publishes peer-reviewed scientific journals, develops internationally recognized Good Practices Reports, and convenes scientific conferences to communicate healthcare evidence to decision makers worldwide.

The response to this consultation was led by the ISPOR Scientific Initiatives Team and our Chief Science Officer. Comments were solicited from ISPOR's Patient-Centered, Oncology, Medical Devices & Diagnostics, Digital Health and Clinical Outcomes Assessment Special Interest Groups, the ISPOR Partnership Group, and ISPOR's Health Technology Assessment Council. The attached document summarizes our comments on specific provisions of the guidance.

ISPOR would be happy to answer any questions about our response, serve as a partner, or participate in any follow-up consultations on the relevant items mentioned in the document.

Sincerely,

Robert M. Abbott
CEO & Executive Director
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Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers

On behalf of the members of ISPOR – the professional society for health economics and outcomes research, we appreciate the Food & Drug Administration's (FDA) efforts in preparing draft guidance which provides answers to common questions concerning firms' communication of health care economic information (HCEI) regarding their prescription drugs and medical devices to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis. This guidance is useful to ISPOR and its members, many of whom specialize in health economics and/or its use in healthcare decision making. ISPOR members reviewed the draft guidance and identified several recurring themes for FDA's consideration, including evidence expectations, intended audiences, modernization and timeliness of HCEI communications, and the selection of current methodological guidance.

Evidence expectations

HCEI varies widely in format, intended use, product type, data source, analytic method, and the expertise of individuals using it for decision-making. Competent and Reliable Scientific Evidence (CARSE) is referenced as the appropriate evidentiary standard, but members noted that CARSE should be interpreted in relation to the type of HCEI, the evidence source, the decision context, and the claim being communicated. For example, budget impact analyses, cost-effectiveness models, observational real-world evidence studies, indirect treatment comparisons, adherence or persistence analyses, clinical outcome assessment-based analyses, and AI-assisted analyses may each require different methodological considerations. ISPOR members suggest that FDA improve clarity by expanding the examples and case studies in the draft guidance. This could include examples demonstrating how CARSE applies across common HCEI scenarios, including real-world evidence, resource utilization studies, model-based analyses, indirect comparisons, and economic analyses using clinical inputs. FDA could also consider developing a repository or companion examples document where additional use cases can be added over time.

Clinical, economic, humanistic, utilization, and implementation evidence may all be relevant to payor decision-making, depending on the context. Resource utilization studies, burden-of-illness analyses, budget impact models, treatment sequencing analyses, and real-world comparative effectiveness studies are examples of evidence types that may be central to HCEI.

It is important that FDA continues to distinguish scientific exchange from promotional communications and to operationalize what "truthful and not misleading" means in the context of HCEI. ISPOR recommends that HCEI be based on appropriate scientific studies and consist of the factual presentation of study results. Members noted that technically accurate economic outputs may still be misleading if they rely on selective model structures, favorable comparator

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choices, omitted evidence, unsupported assumptions, or selective presentation of endpoints, subgroups, or scenarios.

Intended audiences

FDA does well in covering a variety of payor audiences that may receive HCEI but should clarify whether entities acting on behalf of payors fall within scope. ISPOR members raised questions about whether the guidance adequately addresses different organizational capabilities, such as large payers with dedicated HEOR expertise versus smaller organizations with limited internal capacity. FDA could consider using functional criteria for intended audiences, such as whether the recipient is acting in a population-level coverage, reimbursement, formulary, pathway, benefit design, or evidence review capacity. This would help clarify whether entities such as HEOR vendors, evidence review organizations, actuaries, benefit consultants, pharmacy benefit managers, integrated delivery networks, accountable care organizations, employer coalitions, and oncology pathway committees fall within scope.

Modernization and timeliness

The landscape for HCEI formats and practice continues to change. Despite the guidance's expansion into devices, members noted that the examples and recommendations read as largely drug-centric and provide limited information on device-specific issues, such as smaller evidence bases, operator variability, device iterations, procedure-related costs, registry-based evidence, and implementation requirements. Members also noted the need for clearer guidance on software-based products, diagnostics, companion diagnostics, biomarker testing, AI-assisted analyses. Guidance for digital or interactive HCEI tools used for evidence review should also be considered.

For interactive HCEI tools, FDA could clarify expectations for persistent disclosures, version control, audit trails, user-modifiable assumptions, model updates, and documentation of dynamically generated outputs. Similarly to ensuring references, guidance, and other practice standards remain current. FDA should define what is meant by "significant changes" in lines 613-614 and provide examples of when previously communicated information becomes materially outdated. Potential examples include failure to meet a key endpoint, new safety findings, complete response letters, clinical holds, label narrowing, material software or algorithm changes, changes in expected pricing, and changes in eligible population or utilization assumptions. Clearer expectations for when and how payors should be updated would support accountability, transparency, and appropriate use of communicated HCEI across the product lifecycle.

Value-based and outcomes-based arrangements

FDA appropriately states that it does not regulate the terms of risk-sharing or value-based contracts. However, members noted that HCEI used to support these arrangements may

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include outcome definitions, measurement windows, data sources, adjudication rules, patient eligibility criteria, and analytic methods.

Selection of methodological guidance

We appreciate FDA for citing relevant ISPOR Good Practice Reports, including "A Questionnaire to Assess the Relevance and Credibility of Observational Studies To Inform Healthcare Decision Making[1]", "Medication Compliance and Persistence: Terminology and Definitions[2]", and "Consolidated Health Economic Evaluation Reporting Standards (CHEERS) — Explanation and Elaboration[3]". The guidance appropriately references several HEOR good practice standards but has not been updated to include their most recent iterations. As standards continue to evolve, FDA could state that firms should consider the most current applicable version of relevant good-practice recommendations at the time of communication, rather than relying only on specific versions cited in the guidance. ISPOR members recommend that FDA update the references to include:

- Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. *Value Health*. 2022;25(1):3-9. doi:10.1016/j.jval.2021.11.1351
- Academy of Managed Care Pharmacy. AMCP Format for Formulary Submissions 5.0. *J Manag Care Spec Pharm*. 2024;30(4-b Suppl):1-64. doi:10.18553/jmcp.2024.30.4-b.s1

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References

1. Berger ML, Martin BC, Husereau D, et al. A questionnaire to assess the relevance and credibility of observational studies to inform health care decision making: an ISPOR-AMCP-NPC Good Practice Task Force report. *Value Health*. 2014;17(2):143-156. doi:10.1016/j.jval.2013.12.011
2. Cramer JA, Roy A, Burrell A, et al. Medication compliance and persistence: terminology and definitions. *Value Health*. 2008;11(1):44-47. doi:10.1111/j.1524-4733.2007.00213.x
3. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *Value Health*. 2013;16(2):e1-e5. doi:10.1016/j.jval.2013.02.010