CHARME Antitrust Compliance, Operational Approaches, and Best Practices

INTRODUCTION

The Sustainable Purchasing Leadership Council, a nonprofit, multi-stakeholder organization bringing key sustainable procurement expertise and a proven track record of building coalitions and supporting organizations as they design and execute meaningful sustainable procurement strategies, is hosting the <u>Collaborative for Healthcare Action to Reduce MedTech Emissions</u> ("CHARME"), a collaborative initiative focused on reducing greenhouse (GHG) emissions from the value chain for medical devices and supplies.

There can be no doubt that carefully targeted collaborative work by multi-stakeholder teams can drive more significant, more effective and more efficient progress toward reducing GHG emissions in extended supply chains, where organizations across a given industry share many of the same suppliers and customers. However, such collaboration must adhere to acceptable behavior that does not violate antitrust protections meant to safeguard fair competition, pricing and practices. Therefore, as part of the preparatory stages of the CHARME initiative launch, SPLC undertook a high-level review of the potential for antitrust issues in the creation and management of CHARME – and developed appropriate measures to avoid antitrust violations or appearance of the same.

This document provides an overview for CHARME participants of the considerations, methods, and best practices that CHARME is undertaking so that it, and its participants, remain in compliance with antitrust and competition laws.

In developing these CHARME considerations, we have drawn on the insights provided by references listed below the discussion, and particularly on a recent analytical overview¹ published jointly by the Columbia Center on Sustainable Investment (a joint center of Columbia Law School and Columbia Climate School) and Columbia's Sabin School of Sustainability (an academic think tank at Columbia Law School), which addresses this question of antitrust and emissions reduction collaboration directly and in depth.

CHARME OVERVIEW

CHARME is an industry collaborative bringing together health systems, medical device and equipment suppliers, distributors, GPOs, NGOs and other key industry stakeholders to work collaboratively to identify, define, and promote best practices including evaluating the feasibility of industry collaborations contemplated by the 24-month decarbonization roadmap defined in the white paper <u>Catalyzing</u> <u>Collective Action to Decarbonize Healthcare Roadmap for Health Systems and MedTech Suppliers</u> (published in May 2023) to enable more significant greenhouse gas emissions reduction than any one

¹ <u>Denise Hearn, Cynthia Hanawalt, and Lisa Sachs, "Antitrust and Sustainability: A Landscape Analysis," Columbia Center on Sustainable Investment and Sabin Center for Climate Change Law (July 2023)</u>

value chain actor can drive by acting alone. By convening stakeholders with different perspectives, CHARME aims to create a more complete understanding of challenges to enable discovery and development of new strategies through dialogue, shared innovation, and pilot testing. CHARME is also intended, through collaborative effort, to identify and promote methods for the reduction of costs and complexities of transitioning to lower carbon emissions for all stakeholders in the health sector.

The workstreams identified in initial meetings of these parties are as follows:

- Renewable energy Enable access to shared PPAs to enable greater adoption of renewables
- Product innovation Takeback programs, product composition changes, packaging changes
- Product utilization Product durability, reprocessing/reuse, surgical kit composition changes
- Logistics efficiencies Interventions to reduce frequency and improve efficiencies of deliveries (e.g. order consolidation, optimized routes)

CHARME workstreams are designed to develop and recommend best practices that suppliers and health systems can adopt to further emissions reduction, and to identify an array of opportunities for aligned emissions reduction actions. The choice to adopt or participate in any recommended actions will be determined by individual CHARME participants, based on each organization's understanding of its own fiduciary and strategic context.

CHARME'S COMMITMENT TO ANTITRUST COMPLIANCE

CHARME is committed to free and healthy competition and to complying with all antitrust and competition laws applicable to this collaboration and to each of CHARME's participants businesses. Antitrust and competition laws help protect competition, enable open markets, and enhance productivity, innovation, and value for customers. By complying with these laws, CHARME and its participants will all thrive and continue to help the industry and our customers save money and live better all over the world.

All CHARME participants must comply with all applicable antitrust and competition laws in the performance of their responsibilities for and on behalf of CHARME and in alignment with the general principles of CHARME, the SPLC's Antitrust Policy and this operational guidance. In all meetings and all activities, no CHARME participant shall engage in any conduct in violation of the antitrust and competition laws. It is the responsibility of each CHARME participant to recognize potential antitrust or completion concerns as they arise and to report such concerns to CHARME's legal counsel or their own legal counsel.

CHARME's participants are committed to competing vigorously, but also fairly and honestly. Antitrust and competition laws prohibit anticompetitive agreements and behavior, such as price-fixing and predatory efforts to eliminate competition. Penalties for violations can be severe, including hefty fines and prison sentences; therefore, antitrust compliance is paramount.

CHARME'S GOALS AND FOCUS ON COMPLIANCE

CHARME is committed to being a climate or sustainability collaboration that benefits the industry and the community more than any participant could achieve alone, and CHARME is committed to doing so without restraining competition or raising prices. In particular, CHARME will benefit those marginalized communities that tend to suffer most directly from the impacts of climate change. One of the many benefits of procompetitive collaboration focused on GHG emissions reduction is that the initiatives that can only be developed through collaboration are actually likely to reduce the cost of emissions reduction efforts to the industry by reducing duplicative and conflicting emissions reduction efforts in favor of alignment and efficiency. CHARME is focused on strict compliance with the antitrust and competition laws while benefitting communities and general welfare.

Below, we lay out the approaches and actions CHARME and its participants will take to comply with antitrust and competition laws and to safeguard against any appearance of non-compliance.

Alignment with ANSI Essential Requirements for Standards Development

The CHARME collaborative is not a standards development process, and does not intend to result in promulgation of any voluntary or required standards for products, processes, or operations. However its activities are somewhat analogous to standards development, as they involve shared discussion and debate of best practices in a given industry sector, and may eventually provide recommended guidance that could inform adoption of operational, design or business processes.

Given this resemblance, the CHARME project will be structured and managed in alignment with the <u>Essential Requirements of the American National Standards Institute (ANSI)</u>. ANSI is the central standards accreditation body for the United States, and ANSI Essential Requirements outline the standards development process requirements for developing a formally accredited American National Standard. As such, they are highly protective against antitrust and other due process violations that may occur when competitors, customers and other stakeholders discuss business practices. (As a measure of this -- the US Federal government requires process alignment with ANSI Essential Requirements for any standard that it uses or references in a procurement context.)

The Essential Requirements are:

- Openness to participation by any potentially impacted party
- Balance of representation of all potentially interested types of entities
- No monetary barrier of any significance to participation
- No dominance in the process of any single entity or interest group
- Public announcement of the process itself
- Opportunity to weigh in and consideration of all comments/concerns by parties

CHARME is designed and will be managed in alignment with these requirements, as follows:

Openness to participation: The opportunity to participate in the CHARME process is and will continue to be provided openly and transparently to interested parties, and the initiative will

proceed as a "coalition of the willing". Many stakeholders may not wish to participate at the level of intensity required by ongoing CHARME working group discussions; for that reason, processes will be established to solicit and receive input from the wider stakeholder community.

Balance: The CHARME Executive and Steering Committees will carefully monitor the balance of stakeholder types participating in the initiative to ensure that various interests and roles are represented in our discussions. Balance requirements may require working to recruit and support the participation of stakeholder types (e.g. small business, NGOs, sub-suppliers) who might be challenged to participate without financial or other logistical support.

Monetary barriers: While participation in CHARME is fee-based, to support the management and resourcing of the project, opportunities to participate or comment on the outputs of the initiative will be intentionally structured to enable participation without undue financial burden. We have established a fee waiver option for nonprofits, very small businesses, or other financially disadvantaged participants, and have designed governance committees to include all types of stakeholder, independent of financial commitment. As noted above, CHARME will also offer all stakeholders the opportunity to weigh in with comments or through invitations to share relevant information with working groups, without any financial contribution required. We will continue to carefully monitor any financial factors that might limit stakeholders' ability to weigh in.

Dominance of single interests: CHARME's purpose is to convene multiple stakeholder types in a mutually respectful, informative and productive discussion that values and solicits all stakeholder perspectives and needs. We do not anticipate, and will manage the initiative to prevent antagonistic or competitive dynamics – particularly because adoption of any proposed practices and solutions will be entirely voluntary. However, the Executive and Steering committees will monitor and manage the tenor and conduct of group conversations and establish an open-door policy to ensure that any stakeholder or stakeholder group may raise a question or objection if they feel that a single interest type is dominating a conversation or workflow.

Public announcement: The collaboration has been publicly announced in a number of forums during its development, the official launch was held at a free webinar open to the public, and we will continue to publicize its existence, goals and process in a variety of relevant forums.

Opportunity to weigh in: As described above, multiple opportunities will be offered to weigh in on CHARME's work and outputs.

Collective Action Precautions – Alignment and Voluntary Action

The CHARME initiative is designed to enable participants to collaboratively discover points of intervention – whether at the point of design, production, purchasing, delivery, usage, end of life processes or elsewhere in the product lifecycle – where changes can most effectively drive emissions reductions. Wide adoption of the recommended practices developed through this collaborative work

will reduce complexity by providing vetted guidance for adopting realistic and meaningful emissions reduction best practices for health systems and suppliers.

However, CHARME participants will not make any joint commitments to exclude specific suppliers from competitive procurement processes. Further, CHARME participants are not required to commit to adopt any activity or practice that the collaborative may identify and recommend.

While CHARME's intention is to recommend best practices and collaborative action opportunities, all CHARME participants are urged to consider their own organization's adoption of any recommendations individually, based on independent evaluation of their organization's individual risks and fiduciary context. Participants may adopt some, all or none of the recommended actions, based on that independent evaluation.

Information Sharing Precautions

As outlined in CHARME's Confidentiality Policy, participants will not share confidential business information (CBI) that is unrelated to emissions reduction and will withhold confidential business information that would enable others to gain insight into unrelated business practices. Participants also agree to hold confidential any information shared during CHARME meetings, which may specifically include, but will not be limited to, general information concerning supplier (or contracted sub-supplier) design or production processes or other operations, disclosures about internal organizational policies, strategic plans of the organization, and other sensitive information.

To avoid any inadvertent breach of acceptable information-sharing boundaries, when details of operational practices are shared within the collaborative, SPLC or a designated subcontractor will require anonymous collection, aggregation, and sharing of the compiled information. Depending on the degree of complexity and specificity of the information in question, this may be done through anonymous submission of data through simple forms, submission of data to a 3rd party under NDA, or submission of information into a platform using an assigned digital registry ID which is held separate from submitter identification. Information received will be shared back with CHARME working groups in aggregate.

CHARME Antitrust Compliance Operations Detail

In addition to the measures above, all CHARM's participants are further expected to adhere to these additional operational best practices at all times:

Meetings

 Prior to all meetings, including meetings of the executive committee and workstream committees, an official agenda will be prepared and reviewed in advance by SPLC's antitrust counsel. All CHARME discussions will strictly adhere to the written agenda and participants will be encouraged to reach out to their own counsel or SPLC's counsel if discussions deviate from

the agenda. An accurate and thorough record of meeting minutes will be kept and reviewed by antitrust counsel.

- At the outset of all CHARME meetings, a brief statement will be read reminding all participants of antitrust agreements and precautions, and enjoining participants not to undertake listed actions that could constitute antitrust violations.
- For smaller meetings where SPLC and/or its CHARME contractors may not be present, participants are expected to document their own agendas and notes, strictly abiding by the Antitrust Do's and Don'ts and Antitrust Policy, read the Antitrust Statement prior to all meetings, and will be provided with SPLC's counsel contact information for any questions or escalations.

Communications

- Members of the executive committee will be given a 15-minute presentation by SPLC counsel on an annual basis on antitrust compliance best practices and provided with a one-pager of guidance (Do's and Don'ts). The same will be done with members of workstream committees at the time of committee formation and thereafter on an annual basis for its duration. In the event that legal counsel cannot be present to oversee workstream formation, an Antitrust guidance package will be shared with participants (Do's and Don'ts, Antitrust Policy, Statement, Project Pre-Approval form process).
- All external communications shared by the SPLC, including website content, press releases, and white papers, will be reviewed prior to publication by SPLC counsel. Conversely, participants are responsible for circulating their non-SPLC content with their own legal counsel (or SPLC's counsel if they do not have counsel available) prior to its publication.

Other

- The Antitrust Policy and its supporting documents will be revisited on a six-month cadence to ensure they remain up to date and address any new emerging areas of antitrust risk and compliance. CHARME participants' counsels will be given an opportunity to comment.
- SPLC, its contractors, and counsel will periodically review and approve each committee and workstream's composition including any changes that may take place over the 24-month roadmap to ensure stakeholder diversity in all committee and workstream participation.
- Any plans to begin a pilot or test of a solution developed by a workstream committee will be shared via a "Project Pre-Approval" form and reviewed by SPLC's counsel in advance of any launch. Workstream committee members will be informed of this requirement in advance.
- When issuing any reports or briefings to the wider health and MedTech community to enable ongoing awareness of the work of the collaborative, such reports will be accompanied by an invitation to submit comments on the work presented.

• For any antitrust questions or to report a potential antitrust violation to SPLC's counsel, CHARME participants may email: compliance@sustainablepurchasing.org.