

# ***Healthcare Infection Control Practices Advisory Committee Workgroup Guidance***

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## Overview

The Healthcare Infection Control Practices Advisory Committee (HICPAC) was established under Section 222 of the Public Health Service Act [42 U.S.C. §217a], as amended. The role of the HICPAC is to provide advice and guidance to the Secretary, Department of Health and Human Services (HHS); the Director, Centers for Disease Control and Prevention (CDC); the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), CDC; and the Director, Division of Healthcare Quality Promotion (DHQP), NCEZID, CDC regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance, and related events in settings where healthcare is provided. The committee's activities include the development of healthcare infection prevention and control guidelines and guidance, policy statements regarding the prevention and surveillance of healthcare-associated infections and healthcare-related conditions, and new and updated surveillance methodologies related to healthcare-associated infections. More information can be found on the HICPAC website: [HICPAC | CDC](#).

HICPAC utilizes workgroups (WGs) to review relevant published and unpublished data and develop findings, observations and/or outcomes for HICPAC to consider when developing advice and recommendations to the agency officials to whom HICPAC reports. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision-making by HICPAC voting members. The direction, focus, and pace of both HICPAC and the individual WGs are guided by CDC and HHS priorities and the perceived need for expert advice to inform the development of WG products. Such WG products may result in guidelines and guidance from HICPAC.

- WGs are established when HICPAC needs input from subject matter experts (SMEs) on a specific topic.
- WGs are task-oriented, developed in response to specific needs, and terminated when the task has been completed.
- WGs are responsible for collecting, analyzing, and preparing information for presentation, discussion, deliberation, and vote by the HICPAC parent committee in an open public forum.
  - WGs may also request systematic literature reviews be conducted by CDC/DHQP's Office of Guidelines and Evidence Review (OGER) to inform their input and, ultimately, the HICPAC parent committee decisions.
- WGs are non-voting entities and do not directly advise the agency (per the Federal Advisory Committee Act (FACA) and the General Services Administration (GSA) Final Rule requirements).
- WGs may be convened "solely to gather information, conduct research, or analyze relevant issues and facts in preparation for a meeting of the advisory committee, or to draft position papers for deliberation by the advisory committee." [41 C.F.R. § 102-3.40(d) and (e) and 102-3.160(a)].
  - In addition, the following groups are not covered by FACA:
    - Groups assembled to provide individual advice

- Groups assembled to exchange facts or information
- WG members must comply with confidentiality and conflict of interest (COI) disclosure requirements (see Appendix 1).
- A list of WGs that are currently active can be obtained from the HICPAC Designated Federal Officer (DFO).

### **Workgroup Terms of Reference (TOR)**

- TOR are required to be created for each WG, reviewed by the Office of Strategic Business Initiatives (OSBI), Federal Advisory Committee Act Program (FACAP), and the Office of the General Counsel (OGC).
- Approved TOR must also be reviewed by the HICPAC parent committee, and a vote taken by the members for HICPAC records (meeting minutes) in order to establish a new WG. Establishment of a WG should also include identification of the two HICPAC Special Government Employees (SGE) that serve on the WG.
- TOR are shared with all WG members after the WG is formed by the HICPAC parent committee.
- TOR follow a format established by OSBI in consultation with OGC and include the following information:
  - Purpose of the WG
  - Background information
  - Topics under discussion by the WG
  - Description of WG activities
  - Membership
  - Meetings, administration, and timelines
  - Summary of expected product
  - Operations/Process/Timeframe for WG meetings
  - List of participating WG members
  - The role of CDC staff in relation to the WG
  - Duration of the WG
- A record of each WG will be created in the OSBI Federal Advisory Committee Management Portal. All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records (TORs, membership lists, HICPAC slide presentations, COI forms, meeting minutes, etc.) will be uploaded to the Federal Advisory Committee Management Portal. The summary report and other WG products will become part of HICPAC's official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records.
- The WG Chair and WG DFO, in consultation with the HICPAC DFO and, as appropriate, other CDC staff, should re-evaluate the TOR:
  - When major tasks are completed
  - When the WG Chair or WG DFO changes
  - If new issues relevant to the WG arise
  - When events result in shifts in public health priorities

- Annually to make recommendations to the HICPAC parent committee for discussion and decision regarding continuation of the WG and/or WG priorities.

### **Workgroup Participants**

- Each WG must include at least two voting SGE HICPAC members, at least one of whom must be designated as WG Chair.
- A CDC SME serves as the WG DFO.
- Other WG members generally include invited consultants with expertise in the area under review. The WG DFO and chair will solicit recommendations from the HICPAC parent committee as well as work together to identify WG members; the WG should include SMEs with diverse experience and points of view.
  - If a WG member has a COI, all conflicts should be clearly presented to the full WG verbally at least annually. New conflicts should always be reported when they arise. WG member conflicts should also be disclosed to the HICPAC parent committee prior to presentation during public meetings.
  - HICPAC Ex Officio members should not serve as WG members unless they have subject matter expertise that is important for the WG.
  - If an individual SME associated with one of the current liaison organizations listed in the HICPAC charter is appointed to serve as a member of the WG based on their expertise, the WG DFO will make it clear that they are expected to provide their individual subject matter expertise, and not represent the constituency or special interest of their liaison organization.
    - These WG members are expected to document their status as a representative of a liaison organization as a potential COI on the CDC COI forms and verbally to the WG. This conflict will also be disclosed to the HICPAC parent committee prior to presentations during public meetings.
- To facilitate participatory discussion among all WG members, consideration should be given to the overall number of WG members and the expertise each brings to the WG.
  - The recommended size of a WG is <15 members, not including CDC staff supporting the WG. CDC staff are not members of the WG.
- The WG members may seek input from CDC and non-CDC SMEs for consultation or informational presentations that contribute to the WG's tasks and activities. These individuals serve as ad hoc consultants and are not members of the WG. Participation by and contributions of CDC staff must be transparent and evident, to avoid the actual risk of, or the appearance of, undue influence that would compromise independence. The WG and HICPAC parent committee DFOs will ensure that the WG's products are appropriate and not influenced by CDC or any special interest group.
- CDC Staff may also serve in an administrative or supportive function (e.g., technical experts).
  - During HICPAC parent committee meeting presentations, CDC staff should be listed as technical experts separately from WG members on the WG membership slide.

## **Selection of Workgroup Members**

- A CDC full-time (FTE) or permanent part-time employee will be designated by the CDC Center, Office, or Division to serve as the WG DFO with responsibility for the concerned topic or guideline to be considered.
- The HICPAC parent committee DFO will, in consultation with the WG DFO, recruit one SGE voting member from the HICPAC parent committee to serve as WG Chair and at least one additional HICPAC SGE voting member to serve as a WG member.
  - The HICPAC DFO or committee management specialist will send an inquiry to all current voting HICPAC members to assess interest.
  - The WG DFO and HICPAC members and Chair will be responsible for nominating/appointing the WG members including who will serve as WG Chair based on interest, expertise needed for the WG, and availability. WG members can include SGEs from HICPAC and non-SGE SMEs.
  - Additional HICPAC SGE members may serve on WGs depending on the available positions, their expertise, and the number of non-SGE members who are appointed.
- As a HICPAC voting member's term expires, the former Committee member may be appointed to serve as a non-SGE member of the WG at the discretion of the WG Chair and WG DFO based on their subject matter expertise but can no longer represent the HICPAC parent committee.
  - If the WG Chair's term expires, they must be replaced by a HICPAC parent committee SGE voting member.
    - There must be two active HICPAC members on the WG at all times.
  - The new WG Chair will be chosen by the WG DFO in consultation with the outgoing WG Chair and HICPAC Chair but should be approved by the HICPAC DFO in order to ensure balance of workload among HICPAC voting members.
- When new HICPAC members begin their terms, the HICPAC DFO will share a list of the WGs and solicit their interest in joining. The HICPAC DFO will also balance these requests with the need to fill voting member positions on WGs.
- The WG Chair and the WG DFO, in consultation with the HICPAC DFO, will recruit additional members and consultants for the WG.
- The WG DFO should solicit requests for recommendations for SMEs to serve as WG members to facilitate adequate expertise and representation on the WG.
- WG members may change when the WG TOR change and should be reassessed annually and as needed.

## **Conflict of Interest and Confidentiality**

- Non-SGE WG members and CDC technical staff sign COI and confidentiality forms (see Appendix 1) when a WG is formed, when a new COI is identified, and annually. HICPAC SGEs serving on WGs are subject to ethics and financial disclosure requirements for committee members.

- WG member COI should be reported verbally annually at a WG meeting and also be disclosed to the HICPAC committee prior to presentation during public meetings.
- New COI should be disclosed at the beginning of each WG meeting.
- If an individual SME associated with one of the current liaison organizations listed in the HICPAC charter is appointed to serve as a member of the WG, the WG DFO will make it clear that they are expected to provide their individual subject matter expertise, and not represent the constituency or special interest of their liaison organization.

## **Roles and Responsibilities**

- **WG Chair(s)**
  - Attend and participate in WG meetings on a regular basis.
  - Complete timely review of materials as requested.
  - Work with the WG DFO to identify potential WG members.
  - Review COI and membership agreement forms.
  - Review WG membership to ensure necessary expertise is represented.
  - Work with the WG DFO or committee management specialist to set an agenda for WG meetings and timelines of presentations at HICPAC parent committee meetings.
  - Coordinate WG meetings, prepare information for presentations to WG to guide discussions, document roll call, and take minutes (or designate another person [e.g., CDC technical staff member] to do so).
  - Provide overview presentation of WG topics at HICPAC parent committee meetings and other presentations, if needed.
  - Co-author guideline updates, new guidelines, white papers, and other HICPAC WG products.
- **CDC WG DFO**
  - Work with WG Chair, HICPAC DFO, and members to identify potential WG members.
  - Review COI and membership agreement forms.
  - Work with the WG Chair to set an agenda for WG meetings and timelines of presentations at HICPAC parent committee meetings.
  - Coordinate developing agenda proposals, background and briefing documents, and presentations on behalf of the WG for HICPAC parent committee meetings.
  - Complete a timely review of materials and respond to requests from the HICPAC DFO.
- **WG Member(s)**
  - Sign annual membership agreement and COI forms.
  - Attend and participate in WG meetings on a regular basis.
  - Complete timely review of materials as requested.
  - Serve as a SME during WG meetings and calls.
  - Co-author guideline updates, new guidelines, white papers, and other HICPAC products.
- **Ad hoc Consultants**

- Verbally disclose to the WG any COI relevant to the topic being discussed.
- Agree to maintain the confidentiality of WG proceedings.
- Attend and participate in WG meetings on an as needed basis.
- Serve as an SME during WG meetings and calls.
- Ad hoc consultations should present information and respond to questions and answers but not participate in the WG interactive discussions.
- CDC Staff
  - Provide administrative support and technical expertise to HICPAC WGs.
  - Manage the Federal Register public comment process on behalf of the WG and HICPAC parent committee.
  - CDC staff serve as technical experts and not as active members of the WG.
    - CDC staff are aware of agency priorities and of current and anticipated policy issues that may arise in association with the focus of each WG and are responsible for working with the WG DFO to ensure that the focus, direction, and timing of WG efforts remain compatible with the needs of CDC and HHS. Participation by and contributions of CDC staff must be transparent and evident to avoid the actual risk of, or the appearance of, undue influence that would compromise independence. The WG and HICPAC DFOs will ensure that the work products are appropriate and not influenced by CDC or any special interest group.

### **Workgroup Meetings**

- WG meetings will be added to the OSBI Schedule of Meetings in the Federal Advisory Committee Management Portal prior to convening.
- WGs accomplish most of their work through routine (generally monthly or bi-weekly) teleconferences.
- The WG Chair and the WG DFO, in consultation with the HICPAC DFO, should work closely together to determine priorities, processes, direction, and timelines for WG activities.
- WG meetings are closed, and certain guidelines must be observed for WGs to be exempt from FACA open meeting requirements.
  - WGs function in a fact-finding role, do not include a quorum of voting HICPAC members, and do not vote on guidelines.
- As FACA-exempt groups, WGs are not allowed to render consensus advice or recommendations directly to the Federal government.
  - When differing opinions about an issue are expressed during a WG meeting, and the WG Chair and WG DFO want to ensure all members' perspectives are considered, a "straw poll" can be conducted.
  - A straw poll is not a vote, and the goal is not to come to a consensus but rather to document the different opinions of the individual WG members and facilitate continued deliberations.
  - Results of straw polls should be kept within the WG but can be summarized during a presentation at the public HICPAC parent committee meeting.

- WGs are utilized by the HICPAC parent committee to gather and organize information upon which HICPAC can discuss, deliberate, and develop advice and recommendations.
- WGs can and should examine specific topics in detail and define the issues, including the development of findings, observations, and/or outcomes for consideration by the HICPAC parent committee. However, the actual processes of group deliberation resulting in the development of recommendations must occur in the open public forum of HICPAC parent committee meetings in compliance with FACA requirements.

### **HICPAC Public Meetings**

- HICPAC meetings are open to the public and occur up to 8 times per year.
- WG chairs present regular progress updates at the public committee meetings.
- When ready, drafts are presented to the HICPAC parent committee for deliberation, discussion, development of recommendations, and a vote.
- All HICPAC webcasts include time for public comment from members of the public.

### **Termination of Workgroups**

- WGs are designated “task-oriented” and are established when needed and terminated by the HICPAC parent committee once the WG has fulfilled its charge and completed the assigned tasks/activities.
- If the WG has completed its TOR, but a HICPAC document is still in progress, and there is no need for ongoing WG activities, the WG chair and WG DFO will seek approval from the HICPAC members to terminate the WG.
  - The draft document can be circulated to WG members for review and comment until a final draft is ready to be submitted to the HICPAC parent committee for review and decision. In general, WGs should not be terminated prior to completion of the workgroup review process.
  - A WG does not need to stay in existence “in case” a future need arises, or new information becomes available but can be terminated and re-established by the HICPAC parent committee at any time with the original WG members and/or new WG members.
- When the HICPAC parent committee agrees that it is reasonable to terminate the WG (in consultation with the HICPAC DFO), the WG DFO will notify WG members of the decision, thank them for their service and contributions, and inform them of any next steps (e.g., WG findings/outcome review and publication plans, if any).

### **Workgroup Recordkeeping Requirements**

- All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records will be uploaded to the Federal Advisory Committee Management Portal. The summary report and other WG documents or work products will become part of HICPAC’s official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records.



## Appendix 1: Conflict of Interest and Confidentiality Workgroup Membership Agreement

Healthcare Infection Control Practices Advisory Committee (HICPAC) workgroup members should complete the following forms annually:

1. CDC Form 0.1473
2. International Committee of Medical Journal Editors (ICMJE) Conflict Form (or equivalent)
3. HICPAC Workgroup Member Agreement and Conflict of Interest Disclosure for Participants in HICPAC Workgroups (below)

### HICPAC Workgroup Member Agreement

Your name: \_\_\_\_\_

Name of workgroup: \_\_\_\_\_

Date of meeting(s): \_\_\_\_\_

Thank you for your generous contribution of time and expertise as a member of a workgroup (WG) supporting the Healthcare Infection Control Practices Advisory Committee (HICPAC)<sup>1</sup>. Serving as a WG member is an important responsibility. WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the HICPAC parent committee. WGs review specific topics to facilitate informed and efficient decision-making by HICPAC voting members.

It is imperative that all WG members understand and consent to abide by several guiding principles. Please initial each principle below to indicate that you understand it and agree to abide by it in your role as a WG member. Typed initials are acceptable.

**Nature of the advisory role:** \_\_\_\_\_ (initial)

HICPAC assists the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in the development and evaluation of healthcare infection prevention and control guidelines and guidance; the development of policy statements regarding the prevention and surveillance of healthcare-associated infections and healthcare-related conditions; and new and updated surveillance methodologies related to healthcare-associated infections. Per 41 C.F.R. § 102-3.160(a), WGs are convened solely to gather information, conduct research, or analyze relevant issues and facts in preparation for a meeting of the HICPAC parent committee, or to draft position papers for deliberation by the HICPAC. However, WGs do not formulate policy, make, or vote on recommendations.

**Participation:** \_\_\_\_\_ (initial)

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<sup>1</sup> HICPAC refers to the parent committee. More information about the HICPAC is available at: [About | HICPAC | CDC](#)

WGs accomplish most of their work through teleconferences. Participants communicate their individual perspectives and serve as subject matter experts. WGs may appoint subject matter experts from liaison organizations listed in the parent committee's charter; however, the subject matter experts are required to offer their unbiased individual opinions and not those of the organization they represent on the HICPAC as liaisons. Active WGs have a set day and time for routine monthly or bi-weekly teleconferences, which allows standing teleconferences to be arranged and WG members to anticipate and reserve time for these teleconferences. WG members must agree to make their best effort to attend all calls and, over the course of a year, are asked to attend at least 75% of calls. As WG durations are generally limited to 18-24 months, WG members are also asked to participate for the entire time period.

**Confidentiality:** \_\_\_\_\_ (initial)

Unlike HICPAC meetings, WG meetings/teleconferences are not required to be open to the public. The data presented during these meetings might be proprietary, and such information (including discussions and deliberations) should not be distributed to people other than approved WG members. Only WG members, CDC technical staff, and invited consultants can participate. WG proceedings should not be discussed in any personal or professional setting. WG members may not share proceedings, discussions, or slides with people who are not WG members.

**Disclosure of conflicts of interest:** \_\_\_\_\_ (initial)

A participant who has a potential conflict of interest regarding a topic under the purview of a WG on which a person serves should disclose the potential conflict to the WG Chair(s) or the CDC WG Designated Federal Officer (DFO). Regardless of the level of financial involvement or other interest, if the participant feels unable to provide objective input, they must recuse themselves from the WG activities under consideration. The WG process relies on the integrity of each participant to disclose to the WG Chair or WG DFO any real or perceived conflicts of interest that are likely to bias the reviewer's evaluation of a proposal.

Because WG members are most familiar with their own situations, they must: (1) alert the WG Chair or WG DFO about any possible conflict of interest that may impact the perception of impartial and fair activities of WG members and (2) identify and certify on an annual conflict of interest screening form any aspect of the work of the WG where a conflict of interest exists. Please sign below to indicate that you have read and consented to abide by all guiding principles listed above. A typed signature is acceptable.

Signature:

\_\_\_\_\_

Date:

\_\_\_\_\_

## **Conflict of Interest Disclosure for Participants in HICPAC Workgroups**

Workgroups (WGs), as described in the WG Member Agreement, serve a key scientific role in support of the Healthcare Infection Control Practices Advisory Committee (HICPAC). Because WGs do not make or vote on recommendations, do not include a quorum of voting HICPAC members, and report findings to HICPAC rather than the government, WGs are not subject to the open meeting and certain other requirements of the Federal Advisory Committee Act (FACA).

CDC requires non-special government employee (SGE) WG members to disclose conflicts of interest to mitigate potential interference with the integrity and effective functioning of a WG. In order to avoid undue influence or the appearance/perception of a conflict of interest in WG discussions, screening for potential conflicts will be conducted upon establishment of the WG, and annual updates will be collected from non-SGE WG members to ensure that financial or other conflicts are screened for and mitigated as needed. The HICPAC DFO will assist WG Chairs and the WG DFO with the collection of conflict of interest forms; review of the conflict of interest forms will be conducted by the HICPAC and WG DFOs in consultation with the WG Chairs.

Because WG members are most familiar with their own situations, their personal responsibilities include the following: (1) to alert the WG Chair or WG DFO about any possible conflict of interest that may impact perception of impartial and fair activities of WG members; and (2) to identify and certify on an annual conflict of interest screening forms any aspect of the work of the WG where a conflict of interest exists.

When a possible conflict of interest is reported by a WG member, the WG Chair and WG DFO will consult with the HICPAC DFO (and the Office of the General Counsel if necessary) to determine whether the particular situation involves a conflict of interest or an appearance/perception of a conflict of interest which: 1) requires that the WG member not be involved in the WG process or 2) the potential conflict of interest must be disclosed to the WG and HICPAC, but participation in the WG process is allowed.

A conflict of interest exists when a participant has a financial interest in a WG discussion topic that may affect their imputed financial interests or potentially bias their approach to development of options for HICPAC to consider in the development of recommendations. Regardless of the level of financial involvement or other conflict of interest, if the participant feels unable to provide objective input, they must recuse themselves from the WG activities under consideration. The WG process relies on the integrity of each participant to disclose to the WG Chair or WG DFO any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of a WG proposal.

WG members have an ongoing obligation to bring any new information regarding potential conflict(s) of interest to the attention of the WG Chair and WG DFO. In addition, WG members must inform the WG DFO if they are contacted directly by a representative of a manufacturer regarding a product related to WG topics/activities under consideration by the WG on which they serve; the WG DFO will then inform the HICPAC DFO of any such contact and advise accordingly.

There are two procedures for disclosure of conflicts of interest:

1. Annually. All WG members, including federal staff serving on a WG who do not file an OGE450 form, should complete: (a) this form, (b) CDC form 0.1473, and (c) International Committee of Medical Journal Editors (ICMJE) Disclosure Form.
2. Prior to each WG meeting, members should disclose any new conflict(s) of interest during roll call.

### **CERTIFICATION**

I certify that I have read the guidance on Conflict of Interest Disclosure for Participants of HICPAC WGs and disclosed any existing or potential conflicts of interest with any topics under the purview of each WG on which I serve and with the manufacturers of any products under the purview of each WG on which I serve. A typed signature is acceptable.

Signature: \_\_\_\_\_

Work Group: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix 2: Abbreviations and Acronyms

| <b>Acronym</b> | <b>Expansion</b>  |
|----------------|---|
| CDC            | Centers for Disease Control and Prevention                    |
| COI            | Conflict of Interest  |
| DFO            | Designated Federal Officer                                    |
| DHQP           | Division of Healthcare Quality Promotion                      |
| FACA           | Federal Advisory Committee Act                                |
| FACAP          | Federal Advisory Committee Act Program                        |
| FTE            | Full-Time Equivalent  |
| GSA            | General Services Administration                               |
| HCP            | Healthcare Personnel  |
| HHS            | Department of Health and Human Services                       |
| HICPAC         | Healthcare Infection Control Practices Advisory Committee     |
| ICJME          | International Committee of Medical Journal Editors            |
| NCEZID         | National Center for Emerging and Zoonotic Infectious Diseases |
| OGC            | Office of the General Counsel                                 |
| OGER           | Office of Guidelines and Evidence Review                      |
| OSBI           | Office of Strategic Business Initiatives                      |
| SGE            | Special Government Employees                                  |
| SME            | Subject Matter Expert   |
| TOR            | Terms of Reference  |
| WG             | Workgroup   |