



Handbook for HCPs providing services for Cook Medical

Introduction to Cook Medical's approach to engaging
healthcare professionals (HCPs) for services

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Our engagement of healthcare professionals

At Cook Medical (Cook), serving patients is a privilege, and we demand the highest standards of quality, ethics, and service in all that we do. We are passionate about delivering a unique portfolio of medical devices and services while working to make a difference for people and communities. We take pride in our history of innovation, the positive impact we have on patients, and our work in social impact and sustainability around the globe.

Our success is built on great people accomplishing great things together. We continue to innovate and connect with physicians to work together to understand and meet the current and future needs of healthcare professionals and their patients.

As a medical device company, it is important that we engage healthcare professionals to provide services for and on behalf of Cook, including consultancy and comprehensive education and training on the safe and effective use of Cook products.

This handbook is intended to describe our principles and policies when engaging with healthcare professionals for services.

Our commitment

We are committed to practicing ethical business in an ever-changing world, and that commitment comes with certain responsibilities. This handbook provides an overview of how Cook engages healthcare professionals for services in an ethical and compliant way to ensure that our responsibilities and our values are being represented appropriately through our collaboration with you.

We hope that you find this handbook helpful and that you have a positive, respectful, and collaborative engagement with us.



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COOK'S PRINCIPLES & PROCESS FOR HCP ENGAGEMENT

At Cook, we recognize the importance of preserving the integrity of the doctor-patient relationship. During your engagement with us, you should not be inappropriately influenced into choosing a treatment or a medical device for your patient. Accordingly, our key principles and process for healthcare professional (HCP) engagements are designed to ensure we engage with you in a compliant and ethical way to better serve and protect Cook, you, and your patients.

Our key principles for HCP engagement

LEGITIMATE NEED

We engage with HCPs for services only if we have identified a legitimate need for that service in advance.

SELECTION

We apply objective criteria when selecting HCPs for an engagement. HCPs will not be selected in whole or in part based on sales considerations.

NUMBER OF HCPS

We only engage as many HCPs as are necessary to fulfill our needs for a particular service.

TRANSPARENCY

Our relationship with HCPs will be conducted ethically and with appropriate transparency, including Cook complying with all legal and regulatory reporting requirements.

FAIR MARKET VALUE

Any fees we pay to HCPs, whether fixed price or an hourly rate, will be at independent, fair market value rates.

TRAVEL & EXPENSES

We have standard policies on travel and other expenses.

SERVICE AGREEMENT

We enter into written agreements that describe all services to be provided by HCPs, as well as the compensation to be paid.

Our process for HCP engagement

We operate a consistent global approach to engaging HCPs for services. This process focuses on advanced planning, the independent and objective selection of HCPs, identifying and mitigating risks, and compliance with internal standards (e.g., Cook Code of Conduct) and external standards (e.g., laws, regulations, and codes).

Compliance with laws, regulations, and codes

Our principles and process for HCP engagement have been specifically designed to ensure compliance with the various applicable laws, regulations, and codes of ethics. This includes compliance with global anti-bribery and anti-corruption laws, such as the US Anti-Kickback Statute, False Claims Act, Foreign Corrupt Practices Act, and Foreign Extortion Prevention Act. It also includes compliance with codes of ethics and ethical business practices issued by AdvaMed, MedTech Europe, APACMed, and other industry associations globally. Depending on where the HCP is based, this also includes compliance with region- or country-specific requirements, such as transparency reporting requirements and filings required by the anti-gift law

in France. As another example, some national laws and codes of ethics (including the MedTech Europe Code of Conduct) require us to notify your employer healthcare organization (HCO) of our engagement of you and/or get advanced, written approval by your employer HCO of that engagement.

HCO requirements

You are expected to ensure that your engagement by Cook complies with any applicable requirements of your employer HCO (or other employer or affiliated institution). You can contact Cook if you require assistance in complying with those requirements.

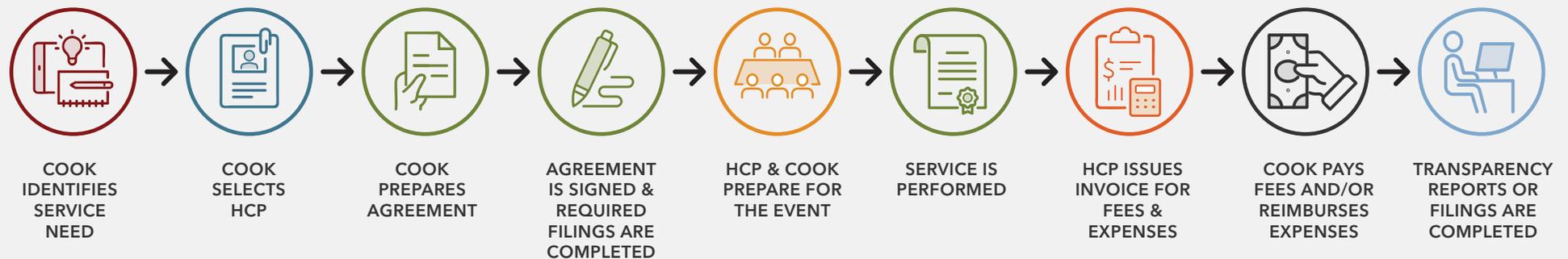
Other interactions with HCPs and HCOs

Although this handbook is specifically for HCPs that provide services for or on behalf of Cook, we may have other interactions with healthcare professionals (e.g., in relation to product development, research, and attending educational and training events) and with healthcare organizations (e.g., in relation to Cook's [charitable donations and grants program](#)) that are not described in this handbook.

HCP ENGAGEMENT BY COOK

Overview

There are various steps in Cook's process for engaging HCPs, including the following:



Planning, legitimate need, and selection

Every HCP engagement by Cook begins with us planning and identifying a legitimate need for HCP services. We then conduct an independent selection process to identify an appropriate and qualified HCP to perform the service. Engagements must not be an actual or perceived inducement or reward to purchase, lease, use, or recommend any Cook product. Accordingly, selection is based on objective criteria, such as the HCP's specialty, years of experience, and number of relevant publications. The selection decision is not made (in whole or part) on the basis of sales (past, present, or future). In addition, similar to other third parties engaged by Cook, a risk-based due diligence exercise is performed for all HCPs and HCOs engaged by us.

HCP agreements

Cook will prepare a Healthcare Professional Services Agreement (HPSA) specifying the services to be provided and the compensation to be paid for those services. The HPSA will also include Cook's standard terms for those services. This Handbook supplements the HPSA and forms part of those standard terms. An HPSA must be signed by all parties before services commence.

An HPSA may be directly between Cook and you, between Cook and the HCO that employs you, or between Cook and a company owned by you. The contracting party will be responsible for various obligations described in this handbook, and all references to "you" in this handbook should be interpreted accordingly. An HPSA is a legal agreement between Cook and that contracting party. Cook will answer any questions that the contracting party may have in relation to the HPSA. That party is entitled to get its own legal advice on the HPSA.

Travel & expense policy

When you are performing a service for Cook, travel, meals, and related expenses may be required. These expenses will be paid in accordance with Cook's policy for HCP travel, accommodation, and other expenses. This policy will be provided to you with the HPSA.

Data privacy

Details of how Cook may collect and process personal data related to HCP services are set out in Cook's Data Privacy Notice for HCP engagements. This notice will be provided to you with the HPSA.

Experience & feedback

Your experience as an HCP performing services for Cook is extremely important to us. We have a program for receiving and implementing feedback from HCPs, to always improve how we engage with you.

COOK'S APPROACH TO PAYMENT

Payment to contracting party only

Cook can only make payment to the party it is contracting with for the services in the HPSA. This allows us to make sure, for compliance and transparency purposes, that we have a contract in place that accurately sets out the services and the payments to be made by Cook for those services. Changes cannot be made after the agreement has been signed, so the party that is contracting with Cook must be carefully considered (i.e., you, a company owned by you or your employer HCO).

Invoicing

When the services are complete, you should submit an invoice to Cook for payment. Payment will be processed in accordance with the terms of the HPSA. An invoice template is available on request.

Fair market value rates

All fees paid by Cook for HCP services shall reflect a fair market value rate for those services. The calculation of the rate will not be based (in whole or part) on sales (past, present, or future).

Cook has a standard process for calculating a fair market value rate. We use





a third-party database that provides objective rates based on factors such as your clinical specialty and country of practice. This third-party database is updated periodically (meaning rates can change from year to year).

The calculated fair market value rate will also be subject to any limit set out in laws or codes relating to amounts payable for HCP services, such as limits set for HCP engagements in France and by the KMDIA Code in Korea. In addition, you are required to inform Cook if your employer HCO sets limits on fees that you can receive for these engagements.

Cook's standard approach is to pay on the basis of hourly rates, as set out in the HPSA. When you are creating and sending an invoice for your services, you are expected to invoice for the actual hours performed, subject to the terms of the HPSA.

No-fee service

An HPSA is required even if no fees are payable for the service.

Transparency reporting

In compliance with legal and regulatory transparency reporting requirements, Cook will, where required, disclose financial and other details of the engagement (including your name) to relevant authorities.

TYPES OF SERVICES

The HPSA will indicate which services you will perform for Cook. These services are defined as follows:

PRESENTATION

Presentations on Cook Medical products and/or related clinical areas, including best practices, techniques for safe and effective use, clinical experiences, data, and clinical information around disease states (including diagnosis and management).

PROCTORING

Clinician-to-clinician advisory support on the use of a Cook Medical product in the performance of a procedure. This may be required in circumstances where the healthcare professional performing the procedure is less experienced with the relevant product or procedure. The healthcare professional receiving the advisory support shall have responsibility for the patient undergoing the procedure.

MODERATOR

Facilitate and guide an event involving multiple participants, such as other healthcare professionals. Includes ensuring the event is conducted in a suitable manner and engaging with the participants and the audience.

CASE REVIEW

Advising on the suitability or use of Cook Medical products (including measuring and sizing, if applicable) in cases where a third-party healthcare professional has responsibility for the patient procedure.

TRAINING

Training and education for Cook Medical employees, distributors, and/or other healthcare professionals, such as training courses, workshops, demonstrations, case observations, and hands-on training on Cook Medical products (including best practices, techniques for safe and effective use, and clinical experiences) and clinical information around disease states (including diagnosis and management).

CONSULTING

Providing evaluation, opinion, and clinical expertise on Cook Medical products and related procedures, disease states, market positioning, and business insights.

Services for Cook

You should only perform a service that has been approved by Cook in advance. Accordingly, if you are contacted by any other party for a service for or on behalf of Cook (such as another healthcare professional requesting proctoring or case review support), you must contact Cook before performing the service.

Presentation services

If performing a presentation, you are responsible for the content of the presentation and ensuring that the presentation is objectively and independently prepared.

- Ensure that the presentation does not infringe any party's intellectual property rights, breach any confidentiality obligations, or include any identifiable patient data.
- Obtain necessary authorizations to use any information included in the presentation.
- Appropriately disclose the paid nature of the engagement to the audience of the presentation.
- Ensure medical educational material does not include advertising or promotional content.
- If required by Cook, provide the presentation in advance for review by Cook. Cook may retain a copy of the presentation for record-keeping and/or regulatory purposes.





Moderator services

If performing a moderator service, you must always aim to facilitate the event in an objective and independent manner, including by guiding any Q&A session. You may also be asked to assist in planning the event.

Training services

Training services include workshops, demonstrations, hands-on training, and/or allowing other healthcare professionals to observe a case being performed by you. Training services can also include you leading a training course, including a mix of case observations, didactic lectures, and hands-on training.

You may provide training simultaneously with the treatment of a patient. If so, it is important for you to be aware that Cook does not, and is not authorized to, provide patient care. In these circumstances, you are responsible for the patient and all aspects of patient care (including arranging all necessary patient consents). As a contractor engaged by Cook, you are not engaged or paid by Cook for patient care (as patient care is not part of the service). Instead, Cook is engaging you for the training provided around the patient procedure, which can include, for example, a presentation in advance of the procedure and a Q&A session afterwards.

All patient data is extremely sensitive and must be protected. If training is provided by you simultaneously with the treatment of a patient, you should omit patient data where possible or anonymize or pseudonymize that data

to remove information that could be used to identify the patient. For example, you should not use the patient's name, and you should ensure that all identifying physical marks are concealed. If that is not possible, the data should be kept to a minimum and limited to what is necessary for the service.

Proctoring services

For a proctoring service, you will provide advisory support to another HCP on the use of a Cook product in a live procedure. The procedure will involve a patient that is being treated by that other HCP, who may be less experienced than you are with the relevant product or procedure. In this role, you may be known as a proctor.

It is important that you are aware that the other HCP is responsible for the patient and that you are a contractor for Cook (i.e., you are not attending the procedure as a treating physician). Cook does not, and is not authorized to, provide patient care. Accordingly, in a proctoring service, you must not provide patient care, perform the procedure, or engage in the placement, insertion, use, or implementation of any product, device, or surgical equipment. Any such act is at your own risk.

You may have practical questions about how to attend a clinical procedure as a proctor rather than as a treating physician. For example, based on questions Cook has received in the past from proctors, we can confirm that it is acceptable for you to wear scrubs, to stand with the healthcare professional performing the procedure, and to review patient information. If you are recorded on a list of healthcare professionals performing the procedure, you should ensure that your sole role as a proctor is noted.

As part of a proctoring service, you may receive the data of patients of a third-party healthcare organization, and you must take steps to protect that data and only use that data for performing the service. This is required to protect the patient and for you to comply with data protection laws.

Cook may, from time to time, issue further guidelines or standards in relation to proctoring services. You are required to comply with these guidelines or standards when providing a proctoring service.

Case review services

The HCP will advise another healthcare professional on the suitability or use of a Cook product. This service is not part of a live procedure, but instead can often be performed in preparation for, and in advance of, a patient procedure or a proctoring service.

As part of a case review service, you may receive patient data from third-party healthcare organizations, and you must take steps to protect that data and only use that data for performing the service. This is required to protect the patient and for you to comply with data protection laws.

Consulting services

The scope of consulting services can vary, but it usually involves you working with Cook to evaluate or provide opinions or clinical expertise on Cook products and related procedures, disease states, and business insights. You may also participate in R&D projects, including usability studies.

Instructions for Use (IFU)

Cook supplies an IFU with each cleared or approved medical device to ensure the safe and proper use of the device. While providing these services, you will only use, or describe the use of, Cook products in accordance with the applicable IFU.



Intellectual property

The HPSA will include requirements in relation to intellectual property, specific to the service to be provided.

Availability and details

You will be contacted by Cook prior to a service taking place to discuss your availability and the expected time commitment. If you are not available to provide a particular service, you should inform the Cook representative who is arranging that service as soon as possible. In addition, if your details or circumstances change in a way that may affect your performance of the services (for example, changing hospital, moving out of the country, or retiring), you are required to inform Cook.

Insurance

Cook recommends that you, as a service provider and independent contractor for Cook, are appropriately insured for the services performed under an HPSA and that you engage with Cook's insurance broker to determine the best options for any required insurance.

Event locations

For all Cook events, you are expected to comply with the requirements of the relevant location or venue, including health and safety requirements and confidentiality obligations. This includes services performed at a Cook location or at a third-party venue, such as a hotel, conference center, simulation lab, or theater.

TRAVELING WITH COOK



Travel & expenses policy

Cook's policy for HCP travel, accommodation, and other expenses will be provided to you with the HPSA.

Cook's appointed travel agencies

Cook has appointed travel agencies to assist with managing travel for you. Contact details for the travel agency in your region or country will be provided to you as part of the booking process. When contacting the travel agency, it is recommended that you provide the relevant booking reference (if available).

How travel is selected

Travel by air and rail is selected based on the most logical and direct routes to align with the start and end times for your service. HCP travel may be booked to arrive within one day before the event start date and depart within one day from the end date of the event. Expenses related to a longer travel duration will not be paid for or reimbursed by Cook.

Travel disruption support

If there is a change to or delay or cancellation of a flight, you should receive an update directly from the airline. To ensure you receive notifications, download the mobile apps for the travel agency and the relevant airline. The travel itinerary from the travel agency will provide contact details that you can use in case of an emergency for travel disruption.

Advice for traveling

Pre-travel advisories are generated by email when international travel is booked via our appointed travel agency. Destination advice can also be accessed via the corporate website www.internationalso.com and logging in using the Cook membership number: 12AYTC000002. Before traveling to another country, you should refer to the medical and security alerts. Different flight classes may be available when required for medical and/or health reasons or when traveling to a high-risk destination. As with all travel, you should ensure that you have your own travel insurance in place. It is your responsibility to ensure that you are fit to travel. When traveling, you should have an ample supply of medications in case of delayed or extended travels.

Medical and/or security emergencies

Emergency contact information will be provided as part of the booking process.





We hope that you find this handbook helpful,
and we look forward to working with you.