



AdvaMed Code of Ethics

Code of Ethics Certification 2020 CHECKLIST for NON- MEMBER COMPANIES

Medical technology companies (both AdvaMed members and non-members) may participate in this certification program. This certification form is for **non-members**. The certification affirms that the company has agreed to abide by the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code") and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. The Certification and the Logo License Program operate on a Calendar Year basis and both are now being accepted for 2020.

A New Certification requires (Attachment A):

Two Signatures

- the signature of the Chief Executive Officer or other senior individual with equivalent responsibilities (CEO);
- the signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO).

Compliance Contact Information for posting on the AdvaMed website with either:

| | | | |
|--------------------------|---|--------|-----------------------|
| <input type="checkbox"/> | Compliance Contact (Individual or Dept.) + Telephone# and/or Email Address (Compliance Hotline Optional) | - OR - | Compliance Hotline |
| | | | |

Electronic Submission:

- Please transmit a PDF electronic copy via email to:
CodeCertification@AdvaMed.org
- Please email a graphic file of your Company's logo to:
CodeCertification@AdvaMed.org

AdvaMed Code Logo License Agreement (Optional)

AdvaMed has developed a distinctive Code of Ethics Supporter Logo ("Logo") for medical technology manufacturers that have executed the Certification of Adoption of the AdvaMed Code of Ethics ("Certification") and wish to use the Logo.



A New Participant in the Logo Program requires:

- A Completed Certification or Renewal Certification form (meeting the requirements noted above)
- A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to CodeCertification@AdvaMed.org
- Proof of completed AdvaMed Code Training by all company representatives
- Contact information to receive the invoice for the Royalty Payment (\$2000/ year)

A Renewal Certification requires (Attachment B):

One Signature

- the signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO), to attest that their company has previously certified and that the company continues to abide by the AdvaMed Code.

Updated Compliance Contact Information:

- Update Compliance Contact Information if it has changed from the previous certification

Electronic Submission:

- Please transmit a PDF electronic copy via email to:
CodeCertification@AdvaMed.org

For Question re: the Certification, Renewal Certification, or the Logo Supporter Program, contact:
Nancy Jackson
202.434.7268
njackson@advamed.org

A Renewal Participant in the Logo Program requires:

- A Completed Certification or Renewal Certification form (meeting the requirements noted above)
- A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to CodeCertification@AdvaMed.org
- Proof of completed AdvaMed Code Re-Training by all company representatives
- Updated Contact information, to receive the invoice the invoice for the Royalty Payment (\$2000/ year)

Attachment A

Non-Member Certification Form
&
Certification FAQs

2020 CERTIFICATION OF ADOPTION OF THE ADVAMED CODE OF ETHICS

Pursuant to the AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”), medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the AdvaMed Code, and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. This certification form is for non-members. This certification requires a company’s Chief Executive Officer (CEO) and Chief Compliance Officer (CCO), or other senior individuals with equivalent responsibilities, to sign and affirm that their company has taken the steps identified below. AdvaMed will list the certifying company on the AdvaMed website in 2020 as a company that submitted this certification. (see www.advamed.org/CodeCertifyingCompanies) AdvaMed retains the right to remove a company from that list, at its sole discretion, for a Company’s failure to abide by the terms of the AdvaMed Certification.

On behalf of _____
(identify Company name or relevant portions/subsidiaries) (“Company”), I certify that, to the best of my knowledge and as of the date of this certification:

I have read and am familiar with the provisions of the AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”), including the Frequently Asked Questions.

I am knowledgeable about our Company’s compliance and ethics program (“Compliance Program”) as it relates to the AdvaMed Code.

Our Company requires all officers, employees, and agents to abide by the AdvaMed Code for all interactions involving U.S Health Care Professionals as that term is defined in the AdvaMed Code.

Our Company has communicated the provisions of the AdvaMed Code to our dealers and distributors with the expectation that they will adhere to them.

Our Company has made a copy of the AdvaMed Code and/or a link to the AdvaMed Code available on our Company’s public Web site.

Our Company agrees to respond to requests for information made to the compliance contact identified below.

Our Company adopted the AdvaMed Code and implemented an appropriately tailored effective compliance program related to our interactions with U.S. Health Care Professionals by taking the following steps:

1. Written Policies and Procedures: Established and implemented policies and procedures that incorporate and foster compliance with the provisions of the AdvaMed Code.
2. Compliance Officer/Committee: Established appropriate oversight and management of the Compliance Program, including: (a) identifying a senior manager in our Company who is responsible for compliance with our Company’s policies and procedures consistent with the AdvaMed Code; and (b) creating a compliance committee or other equivalent process comprised of senior leadership who are actively engaged in the oversight of our Compliance program.

3. Training and Education: Provided effective training using training materials approved by AdvaMed to those employees and contractors whose job requirements make the information relevant on Company policies that are based on the AdvaMed Code, and implemented procedures to ensure ongoing training programs for such new employees and contractors.

4. Lines of Communication: Established effective lines of communication, including a resource for employees to ask questions as well as an anonymous reporting hotline to facilitate internal reporting of suspected violations of Company policies that are based on the AdvaMed Code, and publicized this hotline, or contact information for our compliance department, on AdvaMed's Web site.

5. Auditing and Monitoring: Instituted processes within our Company to conduct internal risk assessments, monitoring and auditing of the Company policies and procedures that are based on the AdvaMed Code and to assess the overall effectiveness of our Company's Compliance Program.

6. Enforcement: Established a disciplinary process for violations of those policies and procedures that support the AdvaMed Code.

7. Corrective Action: Established a process to promptly respond to detected problems or violations of Company policies that are based on the AdvaMed Code.

CEO Signature
(or equivalent) _____

CCO Signature
(or equivalent) _____

Name: _____

Name: _____

Date: _____

Date: _____

Title: _____

Title: _____

Company/
Division: _____

Company/
Division: _____

Mailing
Address: _____

Mailing
Address: _____

COMPLIANCE CONTACT INFORMATION FOR ADVAMED WEBSITE (REQUIRED):

| |
|--------------|
| Name: _____ |
| Phone: _____ |
| and/or |
| Email: _____ |

- OR -

| |
|---------------------------|
| Hotline Contact: _____ |
|---------------------------|

CERTIFICATION FAQs

Q: What does the Certification require?

A: The Certification requires companies to self-certify that they have adopted policies at least as stringent as or policies consistent with the AdvaMed Code of Ethics and implemented the seven elements of an effective compliance program. These elements align with the U.S. Department of Justice Evaluation of Corporate Compliance Programs and HHS Office of the Inspector General Compliance Program Effectiveness Guidance and outline specific programs and processes companies must maintain to ensure effective compliance with the Code.

Q: Are AdvaMed Members required to certify adoption?

A: No. The certification is strictly voluntary. However, AdvaMed strongly encourages all medical technology manufacturers to adopt effective compliance programs consistent with the AdvaMed Code of Ethics.

Q: Who must execute the Certification?

A: The Chief Executive Officer (CEO) and Chief Compliance Officer (CCO) (or their equivalents) of the legal entity seeking to certify must sign and date the Certification of Adoption. For non-U.S. companies, the Certification may be signed by the highest-ranking U.S. corporate executives having authority over the company's U.S. operations. The CEO may wish to consult with legal counsel regarding the implications of certification prior to signing the Certification.

Q: How often must my company complete the Certification?

A: The Certification must be renewed annually.

Q: If my company acquires a new business unit that has not adopted the AdvaMed Code, is my certification still valid?

A: Certifying companies should make every effort to adopt the AdvaMed Code and implement an effective compliance program with regard to a newly acquired business unit as quickly as possible. The certification is made as of the date it is signed and applicable to the company as it existed at that time; a later acquisition would not violate its terms. However, a company should not renew its annual certification the following year if it has not adopted the AdvaMed Code across all of its business units for which the AdvaMed Code is relevant.

The only circumstance in which a company may certify adoption of the AdvaMed Code by a smaller subset of its business units is when an acquisition may have closed too recently before the date of annual certification for the acquiring company to have completed its compliance evaluation and made any necessary adjustments to bring the newly acquired business unit into compliance with the Code. In such cases, the acquiring company may renew its certification for its other businesses but must include a notification that the certification does not apply to the newly-acquired business unit. Unless the company provides a date at which the new unit will be in compliance and covered by the certification, the company will be expected to include the new unit in the following year's certification.

CERTIFICATION FAQS (Cont.)

Q: Is there a standard set of attributes that constitute an effective compliance program?

A: A company's compliance program should be appropriately tailored, meaning it will take into account the company's size, resources, lines of business, and workforce. Many companies' compliance policies and procedures will be tailored to address the specific types of risks that apply to their operations. This could result in some companies' policies and procedures differing from others', while still adhering to an effective compliance program.

Q: How does my company's certification of adoption of the AdvaMed Code relate to the Code of Ethics Supporter Logo?

A: If your company certifies adoption of the Code, you have the additional option of licensing the Code of Ethics Supporter Logo—a symbol of that certification and commitment to compliance. The logo is available to member companies as an AdvaMed member benefit, once they have completed the certification process. The logo may be used on business cards, trade show booths, brochures and in certain other means to visible demonstrate the company's commitment to the AdvaMed Code. Companies are strongly encouraged to take this additional step.

Q: What if my company manufactures pharmaceuticals or biologics in addition to medical technologies covered by the AdvaMed Code?

A: A company may obtain a certification for its medical technology component, division or affiliate, rather than for the company as a whole, and the certification would apply to the business units and employees whose activities make the AdvaMed Code relevant. Any Logo materials used by the company should make this distinction clear.

Q: How do I access AdvaMed-approved training materials?

A: Training materials approved by AdvaMed are accessible via the AdvaMed web site at www.advamed.org/code-ethics or by emailing Nancy Jackson at NJackson@AdvaMed.org.

Attachment B

Renewal Certification

2020 RE-CERTIFICATION OF ADOPTION OF THE ADVAMED CODE OF ETHICS

Pursuant to the AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”), medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. This re-certification form is non-members. This renewal certification requires a company’s Chief Compliance Officer (CCO) or other senior individual with equivalent responsibilities to sign and affirm that their company has previously certified and that the company continues to abide by the AdvaMed Code. AdvaMed will list the certifying company on the AdvaMed website in 2020. (see www.advamed.org/CodeCertifyingCompanies)

On behalf of _____
(identify Company name or relevant portions/subsidiaries) (“Company”), I certify that, to the best of my knowledge and as of the date of this certification:

Our Company has previously certified that we will abide by the AdvaMed Code, and that we have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program.

I further certify that, since the time of our Company’s most recent certification, there have been no material changes to the status of our Company in this regard.

CCO Signature
(or equivalent) _____

Name: _____

Date: _____

Title: _____

Company/
Division: _____

Mailing
Address: _____

UPDATE FOR COMPLIANCE CONTACT INFORMATION ON ADVAMED WEBSITE:

| |
|---------------------|
| Name: _____ |
| Phone: _____ |
| and/or |
| Email: _____ |

- OR -

| |
|------------------------------|
| Hotline Number: _____ |
|------------------------------|

This contact information will be posted to: www.advamed.org/ComplianceContacts

Attachment C

Code of Ethics Supporter Logo License Supplement
and
Logo FAQs
For Member Companies

2020 ADVAMED CODE LOGO LICENSE SUPPLEMENT

AdvaMed developed a distinctive Code of Ethics Supporter Logo (“Logo”) for medical technology manufacturers that have executed the Certification of Adoption of the AdvaMed Code of Ethics (“AdvaMed Certification”) and wish to use the Logo. The Logo is intended to provide a visible symbol of a certifying medical technology company’s commitment to the ethical standards embodied by the Code and to promote awareness about the AdvaMed Code among industry, health care professionals, and the general public.

Companies seeking to use the Logo must sign the following nonexclusive license provision. AdvaMed retains the right to revoke this License for a Company’s failure to abide by the terms of the AdvaMed Certification. This licensing agreement is for non-members.

Revocation of License to Display Logo

1. In the event that AdvaMed, in its sole discretion, determines that a licensee has failed to comply with the terms of this licensing agreement, AdvaMed shall notify the licensee of its determination. If, in the opinion of AdvaMed, the licensee fails to establish compliance with this agreement within 30 days of such notice, AdvaMed shall notify the licensee in writing that the license is revoked. The licensee shall, within ten days of such notice of revocation, cease displaying the licensed logo.

2. In the event that a licensee shall continue to display the logo in violation of Paragraph 1 of this Section, AdvaMed may seek relief in any court of competent jurisdiction. If such court orders any relief sought by AdvaMed, or if the licensee subsequent to the initiation of litigation ceases its use of the logo, the licensee shall reimburse AdvaMed for all litigation costs, including attorneys’ fees.

On behalf of _____
(identify company name or name of relevant portions/subsidiaries), I agree to abide by the following terms to receive a revocable, non-transferable, nonassignable, non-exclusive license to use an unaltered version of the Logo on marketing materials, business cards, and displays at meetings and conferences, and stationery:

- 1) The Logo may not be used on any product;
- 2) The licensee acknowledges and agrees that the right to use the Logo, as well as the actual use of the Logo, is not an endorsement by AdvaMed; and
- 3) The right to use the Logo is subject to the licensee’s annual completion of the AdvaMed Certification, Training and payment of a royalty (\$2000/ year), which royalty may be adjusted by AdvaMed from time to time; and
- 4) The royalty payment is made solely in exchange for the use of the Logo, and such payment does not entitle the licensee to any other benefit or service from AdvaMed.

Signature _____ Date: _____
Chief Compliance Officer (or Equivalent)

Name: _____

Title: _____



Please email the invoice for the royalty payment to:

Name: _____

Use PO or Reference#:

Email: _____

Please email the confirmation of payment receipt and the logo file to:

Name: _____

Email: _____

AdvaMed Code of Ethics Supporter Logo LOGO FAQs



Q: What is the purpose of AdvaMed's Code of Ethics Logo?

AdvaMed's Board of Directors has embraced an ongoing commitment to promote ethical interactions among medical technology manufacturers and health care providers. The Logo is a visible symbol of medical technology manufacturers' commitment to the AdvaMed Code of Ethics and will let health care professionals know at a glance that they are dealing with a company that strives to meet the ethical standards reflected in the AdvaMed Code and has an effective compliance program in place.

Q: How may I use the AdvaMed Code of Ethics Logo?

Licensees may use the Code of Ethics Logo on print or electronic materials to represent their commitment to an effective compliance program and ethical interactions with health care providers. For example, licensees may print the logo on annual reports, promotional material, business cards, stationery and conference banners and signs. The logo may not be used in a manner or associated with text that implies that AdvaMed has endorsed or approved a licensee's products, technology or individual compliance plan or practices.

Q: How do I obtain the right to use the AdvaMed Code of Ethics Logo?

A member or non-member medical technology manufacturer may obtain a one (1) year right to use the AdvaMed Code of Ethics Logo upon submission of a Certification / Renewal Certification and a properly executed License Agreement. Non-member companies must pay a Royalty Fee (\$2000 / year).

Q: Who must execute the License Agreement?

The Chief Compliance Officer (CCO) (or equivalent) of the legal entity seeking the license must sign and date the License Agreement. For non-U.S. companies, the License Agreement may be signed by the highest ranking U.S. corporate executive having authority over the company's U.S. compliance operations. The CCO may wish to consult with legal counsel regarding the implications of licensure prior to signing the License Agreement.

Q: What if I have a complaint about a company using the AdvaMed Code of Ethics Logo?

For any questions concerning a Member's compliance, you may contact the company's Corporate Compliance Officer, whose contact information is available at:

[www. advamed.org/ComplianceContacts](http://www.advamed.org/ComplianceContacts)