

Code of Professional Conduct for Healthcare Ethics & Compliance Professionals

2020 Edition



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Preamble: Purpose, Scope, Objective

The work we do as Healthcare Ethics & Compliance Professionals is aimed at fostering an ethical organizational culture and enabling our organizations to embody in their vision, mission, strategy and activities, the public interest (i.e. the interests of patients and of the healthcare system, as well as those of society and of the environment), striving to ensure a fair, transparent and empowering synergy between organizational objectives and such public interest. This includes setting and maintaining an effective ethics and compliance program with a focus on identifying, preventing, detecting, and mitigating ethics and compliance risks as well as supporting ethical behaviour.

The work we do as Healthcare Ethics & Compliance Professionals is based on the belief that the public interest and the long-term interests of organizations (whether "for profit" or not) are not in opposition but are inseparable to generate sustainability, and on the belief that if a conflict arises, once we have made all reasonably possible efforts to address it, our duty to the public interest must prevail, putting ethics, integrity and trust first. If we are successful in upholding these beliefs in everything we do, we can advance the well-being of patients and the healthcare system, as well as of society and the environment, enabling our organizations to thrive. Without this explicit acknowledgment of, and allegiance to, our public interest role, our profession will not be considered as a profession deserving official recognition.

On this basis, this code aims to emphasize the strategic role our profession plays in ensuring the healthcare industry shapes and implements its strategies with the highest standards of integrity, and to inspire us to reach ever better outcomes in the effectiveness of the ethics and compliance programs we deploy and their positive and sustainable societal impact, preparing our organizations to anticipate future challenges.

In the exercise of our duties, we often face dilemmas that may challenge our ability to respond to conflicts among the various duties that we have, towards the public interest, towards our profession or towards the organizations that employ us. This code is therefore also aimed at supporting us with a sense of direction when faced with those dilemmas, reminding us that our duty to the public interest must always prevail in the end, including, once we have made all reasonable efforts to align our employers, helping us to take difficult but necessary decisions such as resigning and reporting misconduct to the authorities, where appropriate.

This code is not intended to be a compulsory set of rules for all Healthcare Ethics & Compliance Professionals, although its language is intentionally drafted using a prescriptive tone as a reminder of the importance of its content. As mentioned above, it is an instrument of professional and personal self-reflection and introspection to help each of us understand the scale of our duties, recognize our moral commitments and responsibilities, and make the right choices all along the way.

This code has been drafted and promoted by ETHICS¹ – International Society of Healthcare Ethics and Compliance Professionals . With a view to be a shared instrument that includes diverse views, the draft code has been shared for consultation with ETHICS members and several other stakeholders such as public institutions, academics, ethics and compliance professionals, lawyers, trade and professional associations, medical associations, patient organizations and others. Several existing codes and documents were used as a starting point for this code, such as the HCCA² Code of Ethics for Health Care Compliance Professionals. We are sincerely grateful for all the work and excellence these documents have already brought to this important discussion. Starting from that basis, this code has expanded into previously uncodified areas of responsibilities for Healthcare Ethics & Compliance Professionals, intentionally pushing the boundaries of the vision we have for our profession.

ETHICS - International Society of Healthcare Ethics and Compliance Professionals - information is available online at: <u>www.ethicspros.com</u>
HCCA - Health Care Compliance Association - information about HCCA is available online at: <u>www.hcca-info.org</u>



1 Duties to the Public Interest

- 1.1 Healthcare Ethics & Compliance ("HEC") Professionals must conduct their activities in an independent manner that is driven by the best interests of patients, safeguarding unbiased medical judgement, the healthcare system, society and the environment, applying the highest ethical standards, with integrity and respecting applicable laws, regulations and codes at all times.
- 1.2 HEC Professionals must foster and promote a culture of ethics within the organization. Furthermore, HEC Professionals are responsible for setting and maintaining an effective ethics and compliance program with a focus on identifying, preventing, detecting, and mitigating ethics and compliance risks as well as supporting ethical behaviour.
- 1.3 HEC Professionals must not initiate, support or participate in non-compliant activities. They must not disregard, downplay, or ignore such activities.
- 1.4 HEC Professionals must conduct their activities in a transparent and assertive manner, with a duty to be vocal and to speak up in relation to non-compliant activities.
- 1.5 HEC Professionals must cooperate with all the relevant authorities, as applicable and necessary, in a truthful, transparent, accurate and professional manner.
- 1.6 If in the course of their activities, HEC Professionals become aware of actual or potential non-compliant activities that, in their sound judgement, may negatively impact the interests of patients, the healthcare system, society, or the environment, they must not consent to such non-compliant activities and they must do whatever is needed to further investigate and mitigate the related risk. They must escalate them to the highest level of their employer and, if such non-compliant activities continue to be unresolved, they must contemplate as a last resort resigning and informing the highest level of their employer, including, where appropriate, the board, of the reasons of their resignation. They must also consider reporting the matter to the competent authorities, where appropriate.

2 Duties to the Profession

- 2.1 HEC Professionals must act with honesty, judgement, and fairness, both in their professional and personal capacities, embodying personal integrity and acting as role models.
- 2.2 HEC Professionals must promote the credibility of their profession, its value as a guardian of the interests of patients, of unbiased medical judgement, the healthcare system, society, and the environment. They must never bring discredit upon the profession.
- 2.3 HEC Professionals must endorse respectful, fair, and equal treatment as well as human rights and diversity in all aspects of their activities. They must never harass or discriminate against anyone based on any grounds, such as race, color, religion, nationality, age, sex, gender identity or expression, sexual orientation, physical or mental disability, physical appearance, genetics, medical or personal condition, marital status, pregnancy, parenthood, political opinion, trade union membership, professional background, and/or any other discriminatory characteristics. HEC Professionals strive to eliminate incidental and systemic inequalities and biases in all aspects of their activities.
- 2.4 HEC Professionals must respect the confidentiality of the information they become aware of, at any stage, in the context of their activities, and in particular as members of governance bodies or in the course of investigations. HEC Professionals must comply with local laws with regards to confidentiality obligations as these may differ across jurisdictions.

- 2.5 HEC Professionals must know their roles and responsibilities and have the knowledge, skills (soft and technical) and capabilities needed to perform their activities competently. They must continuously strive towards enhancing their own professional and personal development. They have the same duty in relation to other HEC Professionals within their employers, especially in relation to training and mentoring less experienced HEC Professionals.
- 2.6 HEC Professionals must be respectful to and supportive of their peers, inside or outside their employer.
- 2.7 HEC Professionals strive to network and share experiences and best practices with their peers and beyond, with an independent mindset, in a way which protects confidential and commercially sensitive information of their employers and in compliance with the letter and the spirit of competition law.

3 Duties to the Employer

- 3.1 HEC Professionals must implement, maintain and continuously improve effective compliance programs that (a) protect their employers from the risk of breaches, misconduct and penalties, (b) translate applicable laws, regulations and codes into operational guidance, (c) generate competitive advantage and (d) enable their organizations to make the right choices in the interests of patients, the healthcare system, society, the environment and the long-term interests of their organizations.
- 3.2 HEC Professionals are strategic leaders, change managers, and solution-oriented trusted advisors. They use their knowledge, good judgement and conduct their work in a timely, competent, independent, unbiased, authoritative, inspirational, and professional manner.
- 3.3 HEC Professionals must proactively foster and promote a culture of ethics, business accountability for ethical decision making and compliance at all levels of their employer, and beyond. Note that the long-term interests of such organizations are inevitably aligned with the interests of patients, respecting medical independence, the healthcare system, society, and the environment.
- 3.4 HEC Professionals with the appropriate level of seniority must systematically inform the highest level of their employer about the Ethics & Compliance risks affecting the organization and the status of the compliance program, i.e. design, implementation and resources, monitoring, continuous improvement. HEC Professionals must conduct such communications in a manner which is accurate, truthful, and realistic as to the possible outcomes of their work and related activities.
- 3.5 HEC Professionals must promote, with passion and inspiration, a culture of accountability where all employees within their employer, regardless of their role, seniority or function, understand and embody the ownership of ethics and compliance within the activities they conduct, understanding that the ethical reputation, compliance with applicable laws, regulations and codes, and the success of their employer is in the hands of each and every employee.
- 3.6 HEC Professionals must use good business judgement and strive to understand the big picture and systems thinking, including detail orientation where needed. They must strive to understand the context, market specificities, regulatory environment and business strategies and tactics conducted by their employer, so that they can promote compliance programs and provide advice which is relevant, understandable, operational and ensure they are credible stakeholders within their organizations.



- 3.7 HEC Professionals must strive for the Ethics & Compliance function to be an integral part of the management teams of their employer and business unit within their scope of work. They must also provide strategic ethics and compliance advice.
- 3.8 HEC Professionals must stand as role models to all other functions within their employer.
- 3.9 HEC Professionals must foster professional and respectful relations and actively cooperate with all other functions in their employer, seeking and respecting their insight as needed.
- 3.10 When HEC Professionals perform activities in relation to monitoring and investigations, they do so in a professional, respectful, transparent, consistent manner and with diligence. Jointly with Human Resources, they provide advice in the context of related corrective actions and disciplinary measures, in particular regarding fairness, proportionality and being formulated and applied in an unbiased manner, whatever the grade, level of seniority or revenue-generating contribution of those involved.
- 3.11 HEC Professionals must strive to collaborate with HR on employee recruitment, performance and career progression evaluations to provide insight on the ethics and compliance-related performance of the evaluated employees. They must strive to ensure that such insight is factored in and applied in an unbiased manner, whatever the grade, level of seniority or revenue-generating contribution of those involved.
- 3.12 HEC Professionals must not initiate, support or participate in retaliation against any employee who reports actual, potential, or suspected misconduct in good faith³, and they must implement procedures that ensure protection from retaliation. They must not disregard or ignore the fact that others are retaliating against such employees.
- 3.13 If HEC Professionals are confronted with an actual or potential conflict of interest, or even with the appearance of such conflict, they must take the appropriate steps to avoid it or to address it. In particular, they must refrain from monitoring or investigating activities they have approved or advised on.
- 3.14 HEC Professionals must not allow personal or professional proximity or loyalty to anyone in their employer to interfere with the unbiased exercise of their professional duties.
- 3.15 If in the course of their activities, HEC Professionals are not provided sufficient, accurate or truthful information or the bare minimum resources to perform their duties effectively and appropriately by industry standards, they must escalate the issue to the highest level of their employer. If the issue continues to be unresolved, they must contemplate resigning and informing the highest level of their employer, including, where appropriate, the board, of the reasons of their resignation.

3) "In good faith" means that the person making the report believes it to be true at the time and makes the report without the intention of gaining any personal advantage for themselves or those close to them, or of intentionally causing harm to others.

About

ETHICS Vision

We aim to be recognised as an independent international association of professionals, which sets standards of Ethics and Compliance and shapes and influences strategies in the changing Healthcare environment for the ultimate benefit of Patients and Society at large.

ETHICS Mission Statement

We are a visible and transparent network and a think tank of diverse International Ethics and Compliance professionals in the Healthcare sector.

We add sustainable value to Ethics and Compliance professionals by enabling them to manage their professional responsibilities and supporting them in the development of their careers.

We are developing and sharing best practices to anticipate and facilitate new business models in the healthcare sector including through effective education and training, closer collaboration between MedTech and Pharma and other initiatives.

We are delivering Ethics and Compliance perspectives to multiple external Healthcare sector stakeholders, as well as to Ethics and Compliance professionals from other sectors.

We are an independent, not-for-profit association governed by a Code of Conduct.

Our History

Our beginning dates to 2009 and 2010, when a group of European Compliance Officers in the Healthcare Sector met 2 or 3 times per year, to discuss and analyse emerging topics for Compliance professionals particularly in EMEA countries, share best practices and develop internal networking, as well as communication and collaboration with academic institutions.

Prior to 2009, a Compliance leadership Program was designed in 2008 as a collaboration between INSEAD and Johnson & Johnson, for J & J employees, to enhance key leadership competencies necessary to better and more efficiently manage duties and responsibilities in Compliance functions in the Healthcare Sector. The success of this program led in 2010 and 2011 to the development of new sessions open to all professionals in the Healthcare industry, via a specialised Curriculum for Compliance and Ethics professionals developed jointly for SciencesPo, Seton Hall University and INSEAD. Several members of our Association have played a major role, whether in helping to design the programs or as speakers or mentors during the sessions. Our Association will continue to cooperate actively with Academic Institutions or Universities to further develop training programs and professional curricula.

A decision was made in 2011 by the founding members of our Group to move from informal meetings into a more formal structure and to create an Association. Formalising our existence meant, permanently increasing the complexity and importance of our work and laying a foundation for taking next steps on items that are be beneficial to the many Compliance and Ethics professionals within our organisation. ETHICS was therefore incorporated as an Association governed by French law in January 2012.

Contact

For more information visit our website: www.ethicspros.com or send an email at: director@ethicspros.com

