NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

78/CNECV/2014

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Opinion on a "Code of Ethics for the Health Sector"

(April 2014)

CNECV

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1. INTRODUCTION

The current Opinion has been requested by The Minister of Health on a draft Ministerial Order for a frame of reference regarding the adoption of a "Code of Ethics" for services of the Ministry of Health based on the "need for adoption and definition of a standard ethical conduct to be carried out in the relations between all the services and organizations of the Ministry of Health and the citizens", which shall be complied with.

1.1. The Government has the mission of defending and promoting values that have become universal or that have achieved extended compromise in the health area – promoting health and the dignity of the human being – which affect everyone that, direct or indirectly, work in this area or benefit from the services rendered in the National Health System, in the National Health Service (SNS) and also in the private sector.

1.2. Working in the health area is not the same as working in any other professional area: its own values lead to special duties and care[1] to all who intervene in a multidisciplinary way.

1.3. Therefore, professions in the health area have in common an "internal morality"[2], which means the achievement of specific and "internal goods"[3] and also the duty of collaboration and mutual respect among the various participants.

1.4. Such is the specific case of respect for the user's[4] dignity, transparent decision making, accountability in health management, equity of access to healthcare services, commutative justice (for instance, through the adequate relation between value and price[5]) and distributive justice (equity of access and distribution of the necessary resources[6]).

1.5. One of the first values to consider is the patient's dignity, and one of its correlates is the duty to ensure that individual privacy and confidentiality are respected.

1.6. In all that concerns health institutions, transparency values and accounts rendered are paramount: hence the need for the public declaration of interests[7] to be mandatory, a duty that carries out positive moral values and of which no one should be exempted.

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[1] Smith R, Hiatt H, Berwick D. A Shared Statement of Ethical Principles for Those Who Shape and Give.
[2] Fuller, Lon L. *The Morality of Law*. New Heaven, Yale, 1969.
[3] MacIntyre, Alasdair. *After virtue*, University of Notre Dame Press, Indiana, 1981.
[4] Considering the difficulty in finding a wide term to refer all those who resort to health entities – namely a Hospital, Health Center, Hospital Center or any other entity where scientific research is conducted -, the term "User" was considered the most adequate to name patients, users or other beneficiary of the services rendered.
[5] Gracia, Diego. *Valor y precio*. Triacastela, Madrid, 2013.
[6] National Council of Ethics for the Life Sciences. Opinion 64/CNECV/2012 on a Decision Model for Financing the Cost of Medicines.
[7] National Council of Ethics for the Life Sciences. Opinion 72/CNECV/2013and Recommendations concerning Declaration of Interest and Conflict of Interest in Health and Biomedical Research.

1.7. The declaration of interests must not be restricted to health professionals. It ought to equally involve all who professionally deal with the health institution and develop a relation with the users of the services there rendered.

1.8. Building and transmission of values is carried out by fulfilling the respective duties, which in turn bring life to values[8], effectively achieving them.

1.9. The existence of a "Code of Ethics for Health" with a common core shared amongst all health professions and institutions constitutes a means of promoting conscience and a way to educate and foster those same values, revealing some that might still be latent or non-explicit.

1.10. Everyone who works in health institutions – public and private – or whose work refers to those institutions (and which, by any means, have access to the patient's identity and/or elements of his clinic history) shall identify, clarify and recognize the ethical values (specific and common) of his or her occupation and turn them into reality.

1.11. The development of a code of ethics with a common core to every health institution and for everyone who work therein is a way to promote positive conducts and habits and a moral culture of responsibility.

Such moral culture contributes to an education in the ethical values that shall continue to be the motto of the health institutions and there be improved. Thus, the existing reality and practice gain added value, besides spreading these values to the public in general and strengthening the relations of confidence and collaboration with the institutions.

1.12. The aim here involved greatly exceeds the one of those – health professionals, as doctors, pharmaceuticals and nurses – who are already included in proper Deontological Codes.

1.13. These Deontological Codes have another scope and functionality which the present opinion does not intend to call into question.

1.14. Given the enormous diversity of services and organizations that are tutored, supervised or regulated by the Ministry of Health[9], it is important that each one of them has the necessary autonomy in order to - along with the respective ethical committee, and going beyond the general and abstract rule - elaborate and establish the respective code of ethics, taking into account the specific different tasks that arise and specifying the content of the duties resultant from the ethical values in question.

In some cases, the codes may have a set of universal principles of ethical conduct, mainly stated in the common and shared core; in other cases their nature may be more

[8] Gracia, Diego. *Construyendo valores*. Triacastela, Madrid, 2013.

[9] Hospitals, Health Centers, Social Institutions, Investigation Units (ex: Instituto Nacional de Saúde Doutor Ricardo Jorge, I.P. [INSA, I.P.], Comissão de Ética para a Investigação Clínica [CEIC]), regulation and inspection (ex: Direção-Geral da saúde [DGS], Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. [INFARMED, I.P.], Inspeção-Geral das atividades em Saúde [IGAS]), administration (ex: Administração Central do Sistema de Saúde, I.P. [ACSS, I.P.], Administrações Regionais de Saúde [ARS]), among others.

connected to the ethical problems of investigation in biomedicine; to scientific writing; to ethical principles of authorship and publication. Others shall address mainly ethical problems in supportive care; others will relate to ethical matters in administration and regulation, independence and transparency of advisers and consultants whose declarations of interests ought to be public and accessible, as defended by CNECV[10]; and others still with inspection of health institutions (hospitals, doctor's offices, pharmacies).

1.15. In any case, in the health institutions work: managers, administrators, advisers, consultants, administrative officers, various service renderers (*ad hoc* or regularly), insurance agents, social assistants, health professionals (doctors, nurses, pharmaceuticals, diagnostic technicians, auxiliary, psychologists, nutritionists, therapists) investigators, volunteers and other collaborators, also intervening journalists about health matters.

Everyone should respect the absolute confidentiality and privacy of users with whom they maintain a professional relation, whether its nature is direct or indirect. We highlight that in state entities, neither every intervenient necessarily has a public career, nor does he have public duties at the time.

1.16. Notwithstanding the content of the previous item, the current Opinion is restricted to answering the requested, based on the documents proposed.

2. ANALYSYS OF THE PROJECT'S "FRAMING"[11]

In this context, CNECV greets and supports the initiative of the Minister of Health of proposing the EPE Hospitals and other services and organizations of the Ministry of Health a frame of reference for the adoption of a "Code of Ethics for Health", «with the objectives of promoting the values of the continued mission, reinforcing the trust relationships with the *stakeholders* and clarify the principles of conduct which managers, other people in charge and collaborators shall comply in their relationships, whether reciprocated, whether with third parties».

The document submitted to CNECV on the 14th of February 2014 for its appreciation and opinion presents a set of ideas and proposals that are well considered in its intrinsic substance. It is however recommended to better clarify what is proposed, that the structuring and the project's presentation shall be submitted to changes, amendments and supplements that will be further suggested.

[10] National Council of Ethics for the Life Sciences. Opinion 72/CNECV/2013and Recommendations concerning Declaration of Interest and Conflict of Interest in Health and Biomedical Research.

[11] According to the title given by the original document submitted to CNECV review.

The project presented consists of two «Annexes»: annex I, entitled "*Frame of Reference"*, with 20 items; and annex II, entitled "*Code of Ethics. Standard Reference for article to elaborate",* composed of five chapters, respectively: 1. Introduction, 2. Aim of application, 3. Objectives, 4. Principles, 5. Good practices. The main part of this Project of Code of Ethics – henceforth designated Project – is located in annex II, in which chapters 3 to 5 are considered the most important. This Opinion begins with an analysis that follows-up the project's text, step by step.

2.1. Analysis of annex I «*Frame of Reference*»

This annex contains, as above mentioned, 20 items. We assume the permanence of annex I is justified, but it must be discussed. Its explanation is proposed in the introduction included above.

Items 1 (Relation with the citizen) and 2 (Public service) need clarifying when respectively referring to «relation with the citizen» and «public service»; it is not immediately clear the difference between the terms (public and citizen). In fact, item 1 refers to the attitudes of the care providers and its collaborators, in general, while item 2 refers to the effects of those attitudes in users. The key element lies in the «rights and duties» that care providers must «ensure» and which citizens or users must «be aware of». These two items should be amended and turned into one sole item and in a clearer way.

Item 3 (Priority Service and people with physical disability), is totally pertinent given the reinforcement of the importance of proper conditions of accessibility and service.

Item 4 (Right of citizen participation) would benefit with a clarification of its wording or, alternatively, its suppression. In fact, it is not understandable how the «right of citizen participation» is «ensured by direct communication with citizens»; communication from whom to whom? Which kind of «reunions and conferences»?

Item 5 (Systems of documental management) focuses more on the matters of the hospital operation efficiency than on ethics. The main ethical question concerns the concept of «safety», referred as last word. So, this concept ought to be developed in its ethical dimension.

Item 6 (Citizen participation in the activity of the regulatory entities) may be ambiguous and the second half of the sentence is not very precise: «every time the regulations are not internal and concern the services rendered to citizens» and it does not clarify the beginning of the sentence. Actually, the concept of «citizen participation in the activity of the entities [= Hospitals and Health Centers?] through public visits to web sites» will not be understood by the readers. This item must be suppressed or amended if it relates to the

information the citizens may have access to, through Internet, regarding competences, services or office hours in Hospitals.

Item 7 (Public Consults) should also be amended and clarified. Mentioning «public consults» at the beginning of the sentence, in the context of hospitals that provide medical «consults», does not seem the most adequate, all the more so because the second line mentions «consult period». In other terms, the actual wording does not clearly explain the content of the «act» and of the «diploma» mentioned in this item. There could be a clearer reference, as intended, to a procedural phase of "auditions" or "public discussion", distinct of «consults» - medical acts – there provided.

Now, item 8 (Celerity of decisions and Deadline fulfillment) is totally pertinent considering the benefits for the relationship between the entity and its users.

Item 9 (Impediments and excuses) is not understandable without the proper reference to the context of the «decisions adopted by who is in a situation of impediment […]». Medical, administrative or directive decisions?

Item 10 (Impediments and conflict of interests) is very relevant; It will probably be more convenient to keep the first concept in the abovementioned item and limit item 10 exclusively to the conflicts of interests.

Item 11 (Gifts in accordance with duties performed) is very pertinent, given the impartiality values and transparency defended.

Item 12 (Duty of confidentiality) fulfills an important paradigm of protection of potentially sensitive data. It will be therefore necessary to clarify its application to agents or workers whose activity may incidentally interfere with medical, pharmaceutical or nursing services (for example, collaborators in the areas of computing, maintenance or cleaning which, in the performance of their duties, intervene in the location of hospital care (consult or hospitalization rooms).

Item 13 (Acquisition of new competences and knowledge update) is pertinent and actually corresponds to good practices inherent to business ethics. It is only convenient to explain to whom the pronoun “its” is referred to in the expression «its collaborators and agents».

Item 14 (Respect and conservation of the entities’ patrimony) is completely pertinent and has special importance, considering criteria of good use of the allocated resources.

Item 15 (Divulging) focuses on a relevant matter, however a clearer wording could be beneficial (to whom does the possessive pronoun «its activity and mission» refer to?). On the other hand, instead of «preventing the corruption risks», it would be more accurate to say «preventing corruption according to the analysis of the respective predictable risks».

Item 16 (Dematerialization of acts and procedures) concerns more the rules destined to improve the operation and organization of the hospital than the specifically ethical problem. The ethical aspect indirectly relevant focuses on the transparency of the procedures, namely electronic payments.

Item 17 (Crossed information among entities) deserves approval, in the sense that it can turn care services faster and more effective. It is highlighted the importance of safeguarding the confidentiality of sensitive data at all times. Just as the previous item, it would be more adequate in a code of good management procedures, as it focuses on the ethics from the perspective of rationalizing the available resources, which is related to distributive justice, equity and access priority.

Items 18 (Evaluation of the service quality) and 19 (Internal audit) ensure the need of evaluation. Due to its relevance, both items should be clearer: item 18 proposes an evaluation *ab extra*, that is, performed by people – users, patients – who turn or have turned to the entity's services; its «anonymous» character and the «annual publication of the results achieved» are totally justified. It should also be added that evaluation shall also focus on the services of the administrative staff.

Item 19 is focused on the *ab intra* evaluation: internal audit. This is necessary, but, as before mentioned regarding items 16 and 18, this evaluation concerns the quality of the hospital care provided.

Just as they are presented and written, the items do not firstly focus on the ethical dimension, but on inquiring the satisfaction level, in general, of the «services rendered by the entities».

Item 20, dedicated to «fulfilling and monitoring the application of the code of ethics and conduct», is highly relevant. However, it seems to combine two matters: a permanent evaluation in real-time and, on the other hand, the reaction to the evaluation (which may also include the matter of the sanction). Nevertheless, the «mechanisms of internal control» – a particularly sensitive and complex subject – may contribute to the development of more ethical attitudes in the midst of the Hospital.

2.2. Analysis of annex II - «*Code of Ethics*»

First Chapter. Introduction.

The first chapter comprises six brief paragraphs. The intrinsic content is completely pertinent, but the order of presentation combines, on the one hand, the general (§§ 1, 2) and the particular (§§ 3, 6); and on the other hand, it seems to mix the global aims with (§ 4) the

means (§§ 5, 6). For this reason, its particular content will be later repeated, sometimes almost literally. In order to avoid these redundancies, the chapter should exclusively stick to general considerations, namely to limit itself to §§ 1, 2, 4 and 6 (first half until «public interest»).

The detailing of § 5 contains terms or situations not very clear or poorly developed («informality»; «dominant positions», «regulation system…»). It is recommendable for the introduction not to develop examples, and to limit itself to announce the most important parts of the code.

Second chapter. Aim of application.

Item 1 would gain in detailing the proposed even more, explicitly referring administrative services as well as maintenance and cleaning services.

Third chapter. Objectives.

It is recommended for the chapter to be initiated by item «b», which is written in a positive manner.

In general terms, it would be necessary to distinguish the objectives of more professional nature from the objectives which are more specifically ethical: for instance, the items «d» and «e» concern quality, in professional terms, of the services rendered, as opposed to the items «a», «c» and, to some extent, «f».

As previously mentioned, the concepts of *informality* and of *dominant positions* ought to be clarified - for example, «improper use of the vulnerability of the dialog partners, users», «improper situations of privilege».

It becomes superfluous in item «c» the reference to all values enumerated in the following chapter; for higher clarification of the text, it is recommended to restrict the wording to «Guarantee the continuation of the public interest in full respect for the values mentioned in chapter 4».

Fourth chapter. Principles

In a general way, it would be more accurate to name this chapter: *Values, principles and rules.*

From its outset, the document seems to put on the same level relative considerations, respectively, to business or organizational ethics, deontological rules and ethical values of personal nature, which would be important to define and differentiate. It would be therefore

convenient to distinguish the values related to the rules of professional nature - «efficiency», «professionalism», «debureaucratization», «competence» … - from the rest, more specifically connected to personal ethics, for instance: «loyalty», «respect», «good-faith», «transparency», confidentiality».

It would also be convenient to add other principles to be considered, mainly the «respect for the informed consent», «respect for dignity» and «respect for the vulnerability» of the citizens who refer to the services of the hospital or health institution in general.

Fifth chapter. Good Practices

The CNECV considers that this chapter would benefit in clearness by being divided into two parts, that is, by transforming its two first divisions into autonomous chapters, in order to obtain a higher balance in the proposed wording.

A. Relationship with the citizen.

Paragraph 1 (Correction and collaboration) seems to primarily handle the relationship among profession colleagues than their relation with the citizens. In case of maintaining the proposed structure, we find more adequate to change the title of A., therefore: «Relationship between collaborators and service renders and between these and the citizens». It is also recommended to reformulate this first paragraph, as long as it specifies the relation among service renderers, including all service providers of the hospital (without overlooking administrative and maintenance staff). Once reformulated, this paragraph would be in second place, after the actual second.

Item 2 (Public service) should be called «Collaborators, agents and service renderers in view of the citizens».

It would also be convenient to include a new item, which could for instance be the third and named «The citizens according to collaborators, agents and service renderers».

Sub-item a) could be entitled «Communication of information and respect for informed consent». We find the content of the subsections a), b), c), very convenient and pertinent.

For its content, item 2.2. should be re-sent to section B. «Organization and operation».

Item 3 (Priority service) is totally pertinent; (in sub-item (b), there should be added a comma after «the elderly», at risk of changing the phrase intention.

Item 4 (Right of participation) should be integrated in section B, considering that it is related to organization; actually, the task described in this item should not be entrusted to «all

collaborators and agents». On the other hand, its conception is not coherent, as it is not clear how its content articulates with «meetings, conferences or use of electronic means».

Item 5 (Systems of documental management) should also be integrated in section B (Organization and operation) as an item fully related to the duty of confidentiality; in fact, in the actual project it is integrated in item 5 of section B.

Item 6 (Regulatory activity), like the two precedent, ought to be integrated in section B. The actual title of this item 6 is not clear and does not fit the respective content.

Just as items 7 (Procedures regarding public consults) and 8 (Decision deadline) concern rules and regulations and ought to integrate section B.

B. Organization and operation.

The substantial content of all the topics presented is very relevant. The main remarks focus on the presentation and, specially, on the presentation order.

It would be more useful, in clarity and systematization, to distinguish the aspects that concern «organization» in a global view, from aspects that focus on personal attitudes of the service renderers; just as the aspects that focus on evaluation and its follow-up should be separated.

For example, the following topics that concern the general organization of the hospital would be integrated in the field of «*Organization and operation*» (new title):

- Items 5 to 8 of paragraph A2 (*cfr.* above);

- Items 6 to 10 of section B.

In the field «*Ethical rules for care providers*» (new title), there would be contemplated the following items:

- item B1, which title shall simply be «Conflicts of interests», suppressing «Impediments, incompatibilities». In this respect, we remind once again CNECV's Opinion no. 72/CNECV/2013 about Declaration of Interest and Conflict of Interests in Health and Biomedical Research, which reading we refer;

- item B2, «Accumulation of responsibilities»;

- item B3, «Institutional offers»;

- «Participation in congresses and training sessions»: item not addressed and convenient to incorporate;

- to highlight, in this context, the item regarding confidentiality, already mentioned in the Section relative to «Relation between care providers and citizens».

The new items B11 and B12 should be integrated in the field «*Evaluation and follow-up of the evaluation*» (new title), as well as the C paragraph, called «non-fulfillment».

Besides, we believe to be correct that each entity determines its specific forms of evaluation and specifies if it is periodic or continuous, as well as indicates the way how the evaluation results are put into practice. That implies the detailing of the control organizations within the hospital, the periodicity of its interventions and the nature of the efficiency of those interventions.

In short, this section «B» of the actual chapter 5 ought to be an autonomous chapter, with 3 sections, and should incorporate the new titles suggested.

Finally, considering relevant the matters relative to the non-fulfillment, in principle, the code of ethics is not intended to pronounce itself about the eventual application of sanctions; such desideratum shall have specific and adequate regulation.

3. Conclusion of the Analysis.

The conclusive notes consist of a brief general evaluation of the Project, which remarks were noted in the previous section of the Council's present reflection.

Besides the previously suggested, it is convenient to add the following:

3.1. There is no reference to the role of the institutional ethical committees, which should be corrected by altering items no. 2 e no. 3 of the Dispatch. To this effect, we propose the following:

> "*2 - The adoption of codes of ethical conduct aims to contribute for the correct, respectable and adequate performance of public duties and provision of public service, looking for the maximum participation of professionals and agents for determining their terms.*
>
> *3 – The top management of each entity included in this dispatch shall approve or adapt the code of ethical conduct, asking the respective Ethics Committee to collaborate in its writing process, according to the constant model in Annex II to the present dispatch, and submit it to ministry approval, for a maximum period of 180 days counted from the date of publication of the present order. »*

3.2. There is no reference to the role of Voluntary service; although there are already in force various rules of Voluntary service in the national legal order, it would be convenient to highlight its role in the institution, while unpaid collaborator, however, submitted to every ethical rules of the code.

3.3. There is also no reference to the possibility of spiritual or religious service, though its access should be guaranteed by the code.

3.4. CNECV notes that the values, virtues, principles and rules that constitute the forth chapter of the Project ("Principles") are presented without an explanatory note that defines and fulfills them; this option ought to be justified.

3.5. One of the main objections cited in the course of the analysis of the "Code of Ethics for the Health Sector", just as it is presented – besides a structuring that may be improved – can be expressed as follows: there are, indiscriminately announced, considerations that concern the performance of the respective entity (namely its operation and its organization); and considerations that are specifically ethical.

It is true that the ethical dimension pervades every human act, being therefore transversal to every conduct. Yet, there are attitudes specifically ethical that immediately integrate this field of transverseness. In the Project, different levels should be presented separately. That is why, in the improvement suggestions (*cfr*. above, principle of section B from Chapter 5), we have tried to articulate those levels. In fact, in the project considered, the border between a code of ethics and deontological rules and operation rules is not always clear.

3.6. In conclusion, CNECV considers as very pertinent the initiative of the Ministry of Health of proposing a general structure for "Code of Ethics for the Health Sector". However this Council recommends that, to be applied, this code shall give each entity the freedom to densify it according to the specificity of the services it renders, as explicitly recommended in the introduction of this Opinion.

Lisbon, 14 April 2014

The President, Miguel Oliveira da Silva.

Rapporteurs: Counsellors Miguel Oliveira da Silva and Michel Renaud and CNECV Executive Secretary Cíntia Águas.

This Opinion was approved in the plenary meeting on 14 April 2014 and voted. Besides the President, the following Counsellors were present:

Ana Sofia Carvalho; Carolino Monteiro; Francisco Carvalho Guerra; Isabel Santos; José Germano de Sousa; José Lebre de Freitas; Michel Renaud; Pedro Nunes; Rita Lobo Xavier; Rosalvo Almeida.