# Health and Pharmaceutical Law

## Prof. Michele Massa, Prof. Andrea Patanè

***Text under revision. Not yet approved by academic staff.***

COURSE AIMS AND INTENDED LEARNING OUTCOMES

The course aims to provide students with a basic knowledge of the institutions and constitutional and administrative regulations in health and pharmaceutical matters, as well as to delve into some of the more topical issues including reference to the European and international dimension.

Intended learning outcomes

Knowledge and understanding: students will acquire basic knowledge regarding the institutional structure and discipline of the health system and the pharmaceutical sector.

Ability to apply knowledge and understanding: students will be able to understand the fundamental logic of the health system and the pharmaceutical sector which will allow them to address the most relevant and topical legal issues and problems. Autonomy of judgement: students will develop the ability to integrate legal knowledge with that of other disciplinary sectors and to analyse the complexity of phenomena concerning the health system and the pharmaceutical sector; they will also possess critical tools to understand the social, scientific and ethical repercussions of institutional and legal changes.

Communication skills: students will be able to clearly and persuasively communicate the results of the analyses and consequent implications, motivating them in an adequate way for even non-specialist audiences.

Learning ability: students will be able to independently identify paths to deepen their knowledge, in particular to conduct research by consulting texts, specialist journals and databases, and to undertake subsequent studies with a high degree of autonomy.

COURSE CONTENT

1. Historical origins.
2. Constituent choices.
3. First analysis of Art. 32 of the Constitution.
4. Developments up to 1968.
5. Establishment of the National Health System (NHS).
6. The implementation of the NHS and its difficulties.
7. Regionalisation and corporatisation.
8. The impact of the 2001 constitutional reform.
9. Detailed analysis of Art. 32 of the Constitution.
10. Constitutional allocation of legislative powers for health protection.
11. In particular: the standard/minimum levels of healthcare provision.
12. Constitutional allocation of administrative powers for health protection.
13. Forms of connection between State and Regions.
14. Constitutional principles and health finance.
15. Science and law in determining prohibited and mandatory processing.
16. Historical evolution of health and pharmaceutical legislation.
17. The individual and collective dimension of health protection.
18. Care services.
19. Intervention of private individuals in the provision of services.
20. European and international dimension of health protection.
21. National and European regulatory authorities.
22. Organisation of the NHS.
23. Principles of healthcare professions.
24. Principles of healthcare management.
25. Regulation of clinical trials.
26. Pharmaceutical patents.
27. Production and distribution of medicines.
28. Pharmaceutical assistance.
29. The pharmacy profession and practice.
30. Classification of pharmacies and territorialisation system.

READING LIST

Alessandra Pioggia, *Diritto sanitaria e dei servizi sociale*, 3rd edition, Giappichelli, Turin, 2020 (the parts that will be indicated). At the beginning of the course, both in class and via the Blackboard webpage, updated instructions will be given on the manuals and parts of them to be studied, as well as on any other teaching materials, also taking into account the editorial changes that have occurred in the meantime. Additional readings on specific topics will also be made available via the Blackboard webpage.

TEACHING METHOD

Frontal lectures, including the illustration and analysis of jurisprudential and topical cases.

For some of the topics covered in the lectures, in-depth seminars will be organised with the discussion of cases.

ASSESSMENT METHOD AND CRITERIA

The exam aims to evaluate the achievement of the educational objectives described above and the student's preparation, including the maturity achieved in the acquisition of adequate communication and argumentative skills.

The exam takes place in oral form.

In the assessment, clarity and precision of the answers will be particularly appreciated, especially with regard to the fundamental concepts, as well as the coherence and linearity of the analysis, synthesis and argumentation.

An excellent mark will be given to students who demonstrate a complete knowledge of the course contents, together with the ability to move independently and critically between them, as well as to argue and express themselves in organic, precise and technically accurate language.

A good mark will be given to students who demonstrate a detailed knowledge of the course contents and, importantly, of all the fundamental concepts, together with the ability to move between them with a certain degree of independence, as well as to argue and express themselves clearly and correctly.

A fair mark will be given to students who demonstrate an adequate knowledge of the fundamental course concepts, together with the ability to accurately identify the subject of the questions asked during the exam, as well as to express themselves without serious inaccuracies.

A pass mark will be given to students who know the essential features of the course and know how to orientate themselves in principle between these, expressing themselves without serious and repeated inaccuracies.

***NOTES AND PREREQUISITES***

Further information can be found on the lecturer's webpage at http://docenti.unicatt.it/web/searchByName.do?language=ENG, or on the Faculty notice board.