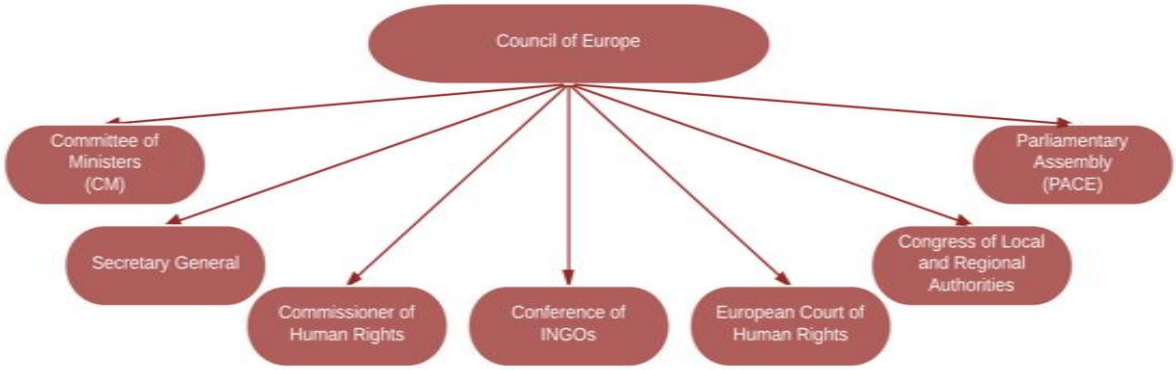
3.2 KEY SOURCES

The standards included in this chapter include those from binding treaties, such as the Convention for the Protection of Human Rights and Fundamental Freedoms (otherwise known as the "European Convention on Human Rights")(ECHR) and the original and revised European Social Charter (ESC), as well as those included in non-binding instruments. The treaties referenced below have come from either the European Union (EU) or the COE. Some non-binding instruments have also been developed by these organizations, but there are others that have emanated from other actors, including civil society groups.

The EU is an economic and political partnership of 28 European member states, created following World War II for the purposes of fostering economic cooperation among its members. Despite its economic nature, the EU considers human rights and equality to be core values and has developed instruments that are relevant to patient care and human rights.EU law has the same level of legal authority as national law for all its member states and must be transposed into national law. As seen below, some EU directives address matters that are relevant to patient care. A "directive" is a type of EU legislative act that sets out goals for member states to achieve, and member states are free to determine how they will devise their laws and implement these goals.

The COEis a non-EU body that focuses on protection of human rights, democracy, and the rule of law in the European region and is located in Strasbourg, France. It consists of seven bodies, known as "institutions," that help the COE carry out its functions. All those states that have ratified the ECHR are members of the COE, and as of this writing, there are 47 of them.[1]Importantly, the COE must not be confused with the European Council (an EU non-legislative body made up of EU leaders that meets regularly to define EU political direction and priorities) or the Council of the European Union (informally known as the "EU Council," a legislative body of the EU).

STRUCTURE OF THE COUNCIL OF EUROPE



LEGALLY binding INSTRUMENTS

EUROPEAN UNION

- **Charter of Fundamental Rights of the European Union**[2]
  This treaty incorporates into EU law a wide range of civil, political, economic, and social rights belonging to all European citizens and residents. It was signed in Nice, France, on November 7, 2000, and became legally binding on December 12, 2007.It is binding on all EU institutions and on EU governments whenever they apply EU law. The charter also acts as an important reference point on human rights obligations for countries outside of the EU, especially those in the process of accession. Refer to Chapter 4 (International

[1]Council of Europe [COE]."The Council of Europe in Brief."Accessed October 29, 2013.
[2]Official Journal of the European Communities. Charter of Fundamental Rights of the European Union.OJ C 364/01. December 7, 2000.

and Regional Procedures) for descriptions of procedures available at the European regional level, including detailed information on monitoring and adjudicatory bodies (e.g., the European Court of Human Rights) and the complaint procedure established by the European Convention on Human Rights.

- **Directive 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare**[3]
  This directive was adopted on March 9, 2011, and entered into force on April 4, 2011. It clarifies the rules on access to healthcare in another EU country, including reimbursement for health care services. The directive is binding on all member states and creates legal certainty on patients' rights, including the right to seek health care abroad and to be reimbursed the same amount that patients would have received if they had sought care in their home country. It also outlines member states' responsibility to provide access to health care in their territory and for ensuring that treatment in other member states meets quality and safety standards and takes into account international medical advances and sound medical practices.

- **Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services**[4]
  This directive was adopted on December 13, 2004, and entered into force on December 21, 2004. It is legally binding on member states and requires them to prohibit discrimination based on sex in the supply of public goods and services.

- **Directive 2000/78/EC of 27 November 2000establishing a general framework for equal treatment in employment and occupation**[5]
  This directive was adopted on November 27, 2000, and entered into force on December 2, 2000. It establishes a "guideline framework" for member states to address employment discrimination. It prohibits discrimination based on religion or belief, disability, age, or sexual orientation.

- **Directive 2000/43/EC of 29 June 2000implementing the principle of equal treatment between persons irrespective of racial or ethnic origin**[6]
  This directive was adopted on June 29, 2000, and entered into force on July 19, 2000. It requires member states to ensure that discrimination based on race or ethnic origin is prohibited in both public and private sectors. The directive lists access to health care as one of the contexts where this type of discrimination must be prohibited.

COUNCIL OF EUROPE

- **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997 (European Convention on Human Rights and Biomedicine)**[7]
  This COE convention sets out certain basic patient rights principles based on the premise that there is a "need to respect the human being both as an individual and as a member of the human species and recognizing the importance of ensuring the dignity of the human being."[8] It is binding on ratifying states.

---

[3]Official Journal of the European Union. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. OJ L 88/45. April 4, 2011.

[4]Official Journal of the European Union. Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services. OJ L 373 of 21.12.2004.June25, 2009.

[5]Official Journal of the European Union. Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation. OJ L 303 of 2.12.2000.December2, 2000.

[6]Official Journal of the European Union. Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin. OJ L 180 of 19.7.2000.July19, 2000.

[7]COE. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine. ETS No. 164. April 4, 1997.

- **European Convention on Human Rights (ECHR)**[9]
  The ECHR is the leading regional human rights treaty, and it has been ratified by all COE member states. It is enforced by the ECtHR, which hands down binding decisions that frequently involve monetary compensation for victims. It should be considered with the European Social Charter as forming the key, complementary instruments protecting human rights across Europe.

- **European Social Charter of 1961 and 1996 (ESC)**[10]
  A COE treaty, the ESC is the leading, regional economic and social rights instrument. It is monitored by the ECSR through a system of periodic state reporting and collective complaints. Originally drafted in 1961, the ESC was significantly revised in 1996, although some states have not ratified the later version and can select which provisions to accept. Given the generality of many of the clauses and given the progressive/liberal approach of the ECSR, patients' rights can be advocated under a number of provisions even in the absence of acceptance of the specific health care guarantees.

- **Framework Convention for the Protection of National Minorities**[11]
  This COE treaty guarantees equal treatment for all ethnic and other minorities. It requires that states take the necessary measures "to promote, in all areas of economic, social, political and cultural life, full and effective equality between persons belonging to a national minority and those belonging to the majority," and such measures are not to be considered acts of discrimination. States are to consider "the specific conditions of the persons belonging to national minorities."[12]

Non-LEGALLY binding Instruments

There are a number of instruments that do not have the legally binding force of treaties but have acquired regional consensus and assist in developing the content of patients' rights. In fact, some of these have been adopted by civil society groups, such as professional associations and non-governmental organizations. Below are a few examples.

- **Declaration on the Promotion of Patients' Rights in Europe: European Consultation on the Rights of Patients, Amsterdam**[13]
  This declaration was issued by the WHO Regional Office for Europe in 1994 and has been influential. It sets the International Bill of Rights,[14] the ECHR, and the ESC as its foundation and focuses on rights to information, consent, confidentiality and privacy, as well as care and treatment. It emphasizes the complementary nature between rights and responsibilities and takes into account the perspectives of health care providers and patients. According to this declaration, patients have "responsibilities both to themselves for their own self-care and to health care providers, and health care providers enjoy the same protection of their human rights as all other people." By outlining patients' rights, this declaration hopes to raise awareness among patients about "their responsibilities when seeking and receiving or providing health care," and thereby create patient/provider relationships based on "mutual support and respect."[15]

- **The European Charter of Patients' Rights**[16]

---

[8] Subsequent additional protocols have been produced on prohibition of cloning (ETS No. 168. December 1, 1998), transplantation of organs and tissues (Treaty ETS No. 186.January 24, 2002), and biomedical research (ETS No. 195. January 25, 2005).
[9] COE. European Convention on Human Rights. ETS No. 5. November 4, 1950.
[10] COE. European Social Charter. ETS No. 35. November 4, 1950.
[11] COE. Framework Convention for the Protection of National Minorities. ETS No. 35. February 1, 1995.
[12] COE. Framework Convention for the Protection of National Minorities. Article 4(2). ETS No. 35. February 1, 1995.
[13] WHO. Declaration on the Promotion of Patients' Rights in Europe. June 28, 1994.
[14] The Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights (ICCPR), and the International Covenant on Economic, Social and Cultural Rights (ICECSR).
[15] WHO. Declaration on the Promotion of Patients' Rights in Europe. June 28, 1994.
[16] Active Citizenship Network (ACN). European Charter of Patients' Rights. November 2002.

Drawn up in 2002 by the Active Citizenship Network, a European network of civic, consumer, and patient organizations, this instrument provides a clear, comprehensive statement of patients' rights. It states:

> As European citizens, we do not accept that rights can be affirmed in theory, but then denied in practice, because of financial limits. Financial constraints, however justified, cannot legitimize denying or compromising patients' rights. We do not accept that these rights can be established by law, but then left not respected, asserted in electoral programmes, but then forgotten after the arrival of a new government.[17]

This statement was part of a grassroots movement across Europe that encouraged patients to play a more active role in shaping the delivery of health services and was also an attempt to convert regional documents concerning the right to health care into specific provisions.[18]This instrument identifies 14 concrete patients' rights that are currently at risk: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment, the filing of complaints, and compensation. Although this instrument is not legally binding, a strong network of patients' rights groups across Europe has successfully lobbied their national governments for recognition and adoption of the rights it addresses.[19]It has also been used as a reference point to monitor and evaluate health care systems across Europe.

- **Ljubljana Charter on Reforming Health Care**[20]
  This instrument was developed by WHO to improve health systems in the European region. It contains a number of fundamental principles to ensure that "health care should first and foremost lead to better health and quality of life for people."[21] Specifically, it recommends that health care systems be people-centric and calls for patient participation in shaping improvements.

- **Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care.**[22]
  Issued by the COE's Committee of Ministers, this recommendation contains strong political and moral authority even though it is not legally binding on COE member states. It focuses on the need to ensure effective participation for all in increasingly diverse and multicultural societies where groups such as ethnic minorities are frequently marginalized.

[17]ACN. European Charter of Patients' Rights. November 2002. Preamble.
[18] The pharmaceutical company Merck & Co., Inc., also provided funding for this movement.
[19] One of the activities of new EU member states during the process of preparation for accession in the EU was adjustment of health care legislation toward European legislation and standards. Many countries, such as Bulgaria, adopted new health law, whose structure and contents are strictly in line with the European Charter of Patients' Rights.
[20]World Health Organization [WHO].Ljubljana Charter on Reforming Health Care. June 19, 1996.
[21]WHO. Ljubljana Charter on Reforming Health Care.
[22]COE. Recommendation Rec No. R (2000) 5. April 30, 2002.