

Personalized Healthcare Competencies Project

Table of Contents

Introduction	2
Competencies	3
General Undergraduate	3
<i>Competency 1: Genetics and Genomics</i>	3
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	4
<i>Competency 3: Informatics</i>	5
<i>Competency 4: The Social and Cultural Environment</i>	6
Undergraduate Pre-Health Professional	8
<i>Competency 1: Genetics and Genomics</i>	8
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	9
<i>Competency 3: Informatics</i>	10
<i>Competency 4: The Social and Cultural Environment</i>	11
Health Professional	13
<i>Competency 1: Genetics and Genomics</i>	13
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	14
<i>Competency 3: Informatics</i>	15
<i>Competency 4: The Social and Cultural Environment</i>	16
Business Student	18
<i>Competency 1: Genetics and Genomics</i>	18
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	18
<i>Competency 3: Informatics</i>	19
<i>Competency 4: The Social and Cultural Environment</i>	20
Law Student	21
<i>Competency 1: Genetics and Genomics</i>	21
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	21
<i>Competency 3: Informatics</i>	22
<i>Competency 4: The Social and Cultural Environment</i>	22
Engineering and Computer Science Student	24
<i>Competency 1: Genetics and Genomics</i>	24
<i>Competency 2: Pharmacogenetics and Pharmacogenomics</i>	24
<i>Competency 3: Informatics</i>	24
<i>Competency 4: The Social and Cultural Environment</i>	25

Introduction

Advances in biomedical science, and especially in genetics and genomics, are enabling an approach to medical care that has been referred to as “personalized healthcare.” Personalized healthcare may be defined as provision of care that is customized to the specific needs of the individual, and includes approaches to health maintenance and prevention as well as diagnosis and management of medical disorders. The concept is based on the idea that outcomes are improved if care is provided that takes account of individual differences, both social and biological.

Implementation of the personalized healthcare model will entail a gradual transformation of medical care at all levels, from public health through primary care. It will require a robust pipeline from basic science discovery through translation to clinical application, which will in turn depend on the availability of an educated workforce and receptivity on the part of the public and policy-makers. A university community, such as UAB, can play a leading role in this effort by preparing students, other trainees, and faculty as researchers, practitioners, and citizens.

This document outlines competencies in personalized healthcare and is intended to catalyze and guide the integration of material related to personalized healthcare into curricula across the UAB community. Rather than prescribe a specific course aimed at a specific audience, this approach is intended to take account of the needs and opportunities to provide education in all areas, including undergraduate and graduate, as well as health professional, biomedical science, social science, business, engineering, *etc.* Like the concept of personalized healthcare itself, the approach is predicated on the idea that pedagogic approaches should be customized to the needs of diverse individuals and should be as flexible as possible.

Competencies

The following sections provide competencies in personalized healthcare that apply to the following groups of students:

- General undergraduate (not planning health professional career)
- Undergraduate pre-health professional student
- Health professional student
- Business student
- Law student
- Engineering student

General Undergraduate

Competency 1: Genetics and Genomics

Use knowledge of the basic principles of inheritance, structure and function of genes and the genome, and the concept of genetic variation to help guide personal and family medical decisions, recognize career opportunities, and contribute to discussions about the contribution of genetics and genomics to health and disease.

Learning Objectives

1. Principles of inheritance
 - a. Describe the basic patterns of Mendelian inheritance.
 - b. Recognize that some traits cluster in families due to multifactorial inheritance.
 - c. Appreciate that genetic factors interact with environmental factors and that neither alone is deterministic.
 - d. Be able to collect and display personal family history information and discuss with health care professionals.
2. Molecular Genetics
 - a. Recognize that genetic information is encoded in DNA.
 - b. Describe the basic structure of DNA and overall mechanism of DNA replication.
 - c. Describe the flow of genetic information from DNA to RNA to protein.
 - d. Recognize that environmental history may influence patterns of gene expression through epigenetic changes.
3. Human Genome
 - a. Recognize that the human genome is the total complement of genetic material that determines inheritance.
 - b. Recognize that DNA in the cell nucleus is packaged into 46 chromosomes.
 - c. Recognize that there is a separate mitochondrial genome that encodes some of the proteins in mitochondria.
 - d. Describe the basic processes of mitosis and meiosis.
 - e. Describe the consequence of major chromosomal abnormalities, such as trisomy 21 (Down syndrome).

- f. Recognize that the nucleotide sequence of DNA in the human genome has been determined.
 - g. Recognize that the human genome consists of a wide variety of elements, not all of which are genes that encode proteins.
 - h. Appreciate that much remains to be learned about the structure and function of the human genome.
4. Genetic Variation
- a. Recognize that DNA base sequence, though more than 99% similar between individuals, still varies significantly from individual to individual.
 - b. Recognize that some DNA sequence variants have phenotypes and others do not.
 - c. Appreciate how DNA sequence variants are a driving force in evolution.
 - d. Describe the major host and environmental factors that may increase risk of mutation.
 - e. Recognize that genetic differences reflect individual ancestry but do not support the existence of discrete racial or ethnic categories.
5. Genetic Testing
- a. Recognize that chromosomal analysis can be performed to diagnose chromosomal abnormalities both prenatally and postnatally.
 - b. Describe the difference between diagnosis of disease and testing for disease predisposition.
 - c. Describe the application of genetic screening programs, such as newborn screening and preconceptional carrier screening.
 - d. Recognize that a sample containing cellular material, such as blood, saliva, or tissue, can be used to test DNA.
 - e. Explain the difference between relative risk and absolute risk of disease.
 - f. Discuss the ethical, legal, and social implications of genetics and genomics and describe laws that address these issues.
6. Cancer Genetics
- a. Recognize that genetic changes underlie the development and progression of cancer.
 - b. Appreciate the role of family history in risk of cancer and the possibility of genetic testing to more precisely define individual risk.
7. Management of Genetic Disorders
- a. Appreciate that genetic disorders may be treated by various means, including nutritional management or medications.
 - b. Recognize career opportunities in clinical care and research related to genetics and genomics.

Competency 2: Pharmacogenetics and Pharmacogenomics

Use knowledge about individual variation in response to pharmaceutical agents to make personal healthcare decisions regarding use of medications and recognize career opportunities.

Learning Objectives

1. Pharmacology
 - a. Recognize that, for a medication to achieve its therapeutic effect, it must be absorbed into the body, reach its site of action, interact with the cell, and finally be cleared from the body.
 - b. Recognize that the same medication may be used for different purposes, and that there are various choices of medication for the same medical problem.
 - c. Explain why different individuals may respond differently to the same medication.
2. Clinical Decision Making
 - a. Explain why a health professional may decide to prescribe a particular medication to a particular individual.
3. Clinical Systems
 - a. Recognize that pharmacogenetic testing is available for some medications, that results of testing do not change over a person's lifetime, and that test results must be available to a clinician at the time when a drug is prescribed.
 - b. Explain the role of the Food and Drug Administration in insuring the safe use of medications in the U.S., including recommendations on pharmacogenetic testing.
 - c. Recognize that specific health insurance payers may have specific criteria regarding reimbursement for pharmacogenetic testing.

Competency 3: Informatics

Use diverse sources of information to guide decisions about personal healthcare, recognizing the strengths, limitations, and possible uses of the information, and recognize career opportunities in health informatics.

Learning Objectives

1. Sources of Information
 - a. Demonstrate the ability to locate and use on-line and print-based sources of health information.
 - b. Recognize the biases and limitations inherent in various sources of information.
2. Storage and Sharing of Information
 - a. Recognize the need to share health information with health providers and the mechanisms and obstacles to making this information available.
 - b. Recognize that medical information available to one health provider may not be accessible to other health providers.
3. Use of Information
 - a. Recognize the opportunities to use informatics tools to formulate and monitor a personal health maintenance plan.
 - b. Recognize the importance of the medical and family history in healthcare.

- c. Recognize the opportunities to utilize health information for research purposes.
- 4. Legal, Ethical, and Regulatory Issues
 - a. Demonstrate awareness of individual rights and obligations regarding the sharing of private health information.
 - b. Appreciate the implications of signing consent forms regarding sharing of health information and biological samples stored in tissue banks.
 - c. Appreciate the distinction between identified, deidentified, and anonymized information.
 - d. Recognize that identified personal health information requires special protections and that there are risks in storing such information in non-protected sites.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to guide personal and family medical decisions, participate in discussions about health policy, and recognize career opportunities.

Learning Objectives

1. Social Roles
 - a. Explain how family and other social relationships contribute to risk of disease and influence dissemination of information about that risk.
 - b. Recognize the role of employment status and type of occupation in contributing to risk of disease and health maintenance.
 - c. Explain how social connectedness of an individual may influence response to disease risk or management.
 - d. Explain how gender roles influence risk of disease and individual response to that risk.
2. Social Status
 - a. Recognize how individual socio-economic status influences risk of disease, perception of that risk, and ability to manage the risk.
 - b. Describe how race and ethnicity influence access to care and the reactions of an individual to disease risk above and beyond socio-economic status
3. Culture
 - a. Recognize that, with regard to culture, within-group differences are greater than between-group differences.
 - b. Explain how cultural factors and patterns of behavior may influence health and risk of disease.
4. Institutions
 - a. Describe the roles of governmental laws, regulations, and financial resources in healthcare utilization of by individuals.

- b. Recognize that research and policy decisions based on study of human populations can be misinterpreted as indicative of biologically based racial factors.
- c. Recognize the role of religious institutions in guiding individuals regarding healthcare decisions.
- d. Describe the various types of health providers, how they interact with individuals in health maintenance and management of disease, and the career options that are available in healthcare.
- e. Explain how health care is financed and the role of third party payers in access to health care, disease prevention, and disease management.
- f. Recognize that advances in medical technologies and knowledge may, at least temporarily, lead to increases in health disparities.
- g. Explain the role of pharmaceutical and medical device companies in development and marketing of drugs and medical devices.
- h. Explain the role of public and private funding in support of medical research.

- c. Recognize career opportunities in developing and managing systems for data access, management, and storage, and point-of-care medical decision support.
3. Use of Information
 - a. Demonstrate awareness of the utility and functions of major bioinformatics databases to analyze genomic information.
 - b. Recognize the opportunities to use informatics tools to formulate and monitor a personal health maintenance plan.
 - c. Recognize the importance of medical information in managing chronic disease.
4. Legal, Ethical, and Regulatory Issues
 - a. Demonstrate awareness of individual rights and obligations regarding the sharing of private health information.
 - b. Appreciate the implications of signing consent forms regarding sharing of health information and tissue stored in tissue banks.
 - c. Appreciate the distinction between identified, deidentified, and anonymized information and the role of unique identifiers in clinical research.
 - d. Recognize that identified personal health information requires special protections and that there are risks in storing such information in non-protected sites.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to guide personal and family medical decisions, participate in discussions about health policy, and recognize career opportunities.

Learning Objectives

1. Social Roles
 - a. Explain how family and other social relationships contribute to risk of disease and influence dissemination of information about that risk.
 - b. Recognize the role of employment status and type of occupation in contributing to risk of disease and health maintenance.
 - c. Explain how social connectedness of an individual may influence response to disease risk or management.
 - d. Explain how gender roles influence risk of disease and individual response to that risk.
2. Social Status
 - a. Recognize how individual socio-economic status influences risk of disease, perception of that risk, and ability to manage the risk.
 - b. Describe how race, and ethnicity influence access to care and the reactions of an individual to disease risk above and beyond socio-economic status.
3. Culture

- a. Recognize that, with regard to culture, within-group differences are greater than between-group differences.
 - b. Explain how cultural factors and patterns of behavior may influence health and risk of disease.
4. Institutions
- a. Describe the roles of governmental laws, regulations, and financial resources in healthcare utilization of by individuals.
 - b. Recognize that research and policy decisions based on study of human populations can be misinterpreted as indicative of biologically based racial factors.
 - c. Recognize the role of religious institutions in guiding individuals regarding healthcare decisions.
 - d. Describe the various types of health providers, how they interact with individuals in health maintenance and management of disease, and the career options that are available in healthcare.
 - e. Explain how health care is financed and the role of third party payers in access to health care, disease prevention, and disease management.
 - f. Recognize that advances in medical technologies and knowledge may, at least temporarily, lead to increases in health disparities.
 - g. Explain the role of pharmaceutical and medical device companies in development and marketing of drugs and medical devices.
 - h. Explain the role of public and private funding in support of medical research.

Health Professional

A health professional student should achieve all of the competencies described under “Undergraduate, pre-health professional,” and, in addition, the following:

Competency 1: Genetics and Genomics

Use knowledge of the basic principles of inheritance, structure and function of genes and the genome, and the concept of genetic variation to assess individual risk of disease, formulate an individualized management plan, and provide support to the individual in maintaining health and/or managing disease.

Learning Objectives

1. Principles of Inheritance
 - a. Collect and interpret a three-generation family history.
 - b. Calculate basic genetic risks associated with Mendelian disorders.
 - c. Describe the major models of multifactorial inheritance and the role of multifactorial inheritance in the genetics of common disorders.
 - d. Explain the role of familial factors to a patient and recognize indications for referral to an appropriate specialist.
2. Molecular Genetics
 - a. Explain the role of genetic factors, including single genes, genetic interactions, and epigenetic marks, in guiding normal or abnormal development.
 - b. Describe the molecular mechanisms of major pathophysiological processes.
 - c. Describe the role of epigenetic marks and the phenomenon of genomic imprinting in the control of gene expression.
3. Human Genome
 - a. Describe the major types and clinical consequences of chromosomal abnormalities.
 - b. Explain the mechanisms of control of the cell cycle and how perturbations may result in diseases such as cancer.
 - c. Explain the mechanisms of control of genes by noncoding RNAs and the roles of these RNAs in disease processes.
 - d. Explain how genomic analysis has led to the discovery of genes that contribute to common and rare disorders.
4. Genetic Variation
 - a. Explain how changes in DNA sequence lead to phenotypic effects that underlie Mendelian and non-Mendelian disorders.
 - b. Describe the major disorders associated with abnormalities of genomic imprinting.
 - c. Recognize how the combination of single genetic variants determines the differential clinical consequences in different populations.
 - d. Explain to patients what is known about the causes of mutations and ways to protect against exposure.

5. Genetic Testing
 - a. Explain the approaches to chromosomal and genomic microarray analysis the typical clinical indications, and the approach to ordering tests.
 - b. Recognize clinical situations where diagnostic or predispositional testing might be appropriate.
 - c. Explain to patients in understandable terms the potential risks and benefits of genetic testing, including direct-to-consumer tests.
 - d. Explain the uses and limitations of exome or whole-genome sequencing.
 - e. Understand and interpret genetic test reports and recognize where specialist consultation is indicated.
 - f. Explain to patients the ethical, legal, and social implications of genetics and genomics and laws that address these issues.
6. Cancer Genetics
 - a. Explain how genetic testing can be used to diagnose cancer and select appropriate therapy.
 - b. Recognize the family history findings that indicate an increased risk of cancer and refer patients to specialists in genetic testing.
7. Management of Genetic Disorders
 - a. Explain to patients the principles and procedure of newborn screening and the appropriate follow-up to abnormal results.
 - b. Collaborate with appropriate specialists in the management of patients with genetic disorders.
 - c. Describe the roles of various health professionals in genetics, including medical geneticists and genetic counselors, and recognize indications for referral.

Competency 2: Pharmacogenetics and Pharmacogenomics

Integrate knowledge about pathophysiology of disease and of individual variation in response to pharmaceutical agents to guide choice of medication, selection of appropriate dosage, and monitoring for response and side effects.

Learning Objectives

1. Pharmacology
 - a. Apply knowledge of disease pathophysiology to select appropriate classes of drugs for treatment of different clinical problems.
 - b. Explain the differences between different drugs that might be used to treat specific clinical problems.
 - c. Explain the basis for individual differences in drug absorption, metabolism, and excretion and the contribution of genetic factors.
 - d. Explain the concept of pharmacodynamics and how different individuals may respond differently to the same drug.
2. Clinical Decision Making

- a. Recognize that pharmacogenetic test information, in addition to medical, family, and social history, and physical examination, may influence initiation of preventative measures and/or treatment.
 - b. Explain the role of genetic testing in guiding choice of medication and adjustment of drug dosage to avoid side effects and maximize efficacy.
 - c. Describe how to order pharmacogenetic tests, access results, and interpret results for clinical decision-making.
 - d. Communicate the basis for clinical decision-making regarding pharmacotherapy to patients.
 - e. List the sources of information available to the clinician to assist in the incorporation of pharmacogenetic information, including access to appropriate specialists, databases, and other web-based resources.
3. Clinical Systems
- a. Describe the roles of different health professionals in development, formulation, prescription, and monitoring of pharmacologic treatments.
 - b. Describe the processes whereby medications are developed, approved, and monitored for efficacy and side effects.
 - c. Recognize that pharmacogenetic tests must be done in CLIA-certified laboratories and that turnaround times must be appropriate to meet the needs of clinical decision-making.
 - d. Explain how decisions are made by health care organizations and payers to include specific medications in formularies or for reimbursement, or the reimbursement for pharmacogenetic testing.

Competency 3: Informatics

Use diverse sources of information to guide medical decision-making, recognizing the strengths and limitations of information sources and recognize career opportunities in health informatics.

Learning Objectives

- 1. Sources of Information
 - a. Demonstrate the ability to use on-line and print-based sources of health information aimed at professionals and identify the sources of information available to non-health professionals.
 - b. Demonstrate proficiency in the access to and use of electronic health records.
- 2. Storage and Sharing of Information
 - a. Demonstrate awareness of policies and procedures for utilizing health information databases, tissue banks, and information sharing.
 - b. Recognize the importance of sharing medical information with the healthcare team involved in care of individual patients
- 3. Use of Information

- a. Demonstrate proficiency in the use of point-of-care medical decision support tools.
 - b. Demonstrate proficiency in the use of essential bioinformatics tools in medical decision-making.
 - c. Explain to patients the use of informatics tools in health maintenance and management of chronic disease.
 - d. Recognize career opportunities in clinical and research informatics.
4. Legal, Ethical, and Regulatory Issues
- a. Demonstrate awareness of individual rights and obligations regarding the sharing of private health information.
 - b. Demonstrate awareness of policies and procedures for consent for patient information sharing and storage.
 - c. Explain to patients the implications of signing consent forms regarding sharing of health information and tissue stored in tissue banks.
 - d. Recognize the risks associated with management of private health information and the approaches to protecting patient privacy.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to guide the management of health and disease in individual patients.

Learning Objectives

1. Social Roles
 - a. Explain how knowledge of family and other social relationships can be used to improve healthcare of individuals.
 - b. Recognize the role of health providers in informing individuals about genetic risks that may apply to family members and the responsibilities to respect privacy of family members.
 - c. Explain how to recognize the social connections of an individual and provide advice to use or strengthen these connections in managing disease risk or treatment.
 - d. Describe the role of the health provider in tailoring medical advice about risk of disease to occupation and employment status.
 - e. Describe the approaches to providing sex-specific advice regarding disease risk and management.
2. Social Status
 - a. Describe the social and structural obstacles to providing individuals of different socioeconomic status access to healthcare and resources available to help overcome these obstacles.
 - b. Demonstrate awareness of racial, ethnic, and cultural disparities in access to healthcare and approaches to minimize these disparities.
3. Culture
 - a. Explain how the approach to providing medical care must be tailored to behavioral norms in different cultural groups.

- b. Explain how knowledge of cultural values and beliefs can help in tailoring medical care and disseminating medical information.

4. Institutions

- a. Describe major governmental laws, regulations, and financial resources and how these influence individual health-related decisions.
- b. Tailor health care advice and management to the religious beliefs and recognize the role that religious institutions may play in health maintenance and management of disease.
- c. Explain how a team approach to health maintenance and disease management is important in improving health outcomes.
- d. Explain the different types of third party payers and the manner in which these differences influence health care decisions by an individual.
- e. Explain to patients the roles of pharmaceutical and medical device companies in development and marketing of drugs and medical devices.
- f. Explain to patients the roles of public and private funding in support of medical research.

Business Student

A business student should achieve all of the competencies described under “General Undergraduate,” and, in addition, the following:

Competency 1: Genetics and Genomics

Use knowledge of the basic principles of inheritance, structure and function of genes and the genome, and the concept of genetic variation to recognize business opportunities, formulate a business plan, and manage a business that provides healthcare services.

1. Principles of Inheritance
 - a. Describe the business models of commercial systems that facilitate collection of family history information.
2. Genetic Testing
 - a. Describe the business models of commercial and academic genetic testing laboratories.
 - b. Explain the regulatory and legal requirements for establishing and running a genetic testing laboratory.
 - c. Explain the role of patent law in genetic testing.
3. Cancer Genetics
 - a. Explain how genetic testing affects the marketing and use of drugs important for treatment of cancer.
4. Management of Genetic Disorders
 - a. Describe the business approach to development and testing of new methods of treatment both in large pharmaceutical companies and in small ventures.
 - b. Explain the intellectual property requirements involved in new drug development and testing.

Competency 2: Pharmacogenetics and Pharmacogenomics

Use knowledge about individual variation in response to pharmaceutical agents to recognize business opportunities and guide business decisions.

Learning Objectives

1. Pharmacology
 - a. Formulate a business case for the development of a new type of pharmacologic agent.
 - b. Analyze the business implications of targeting an existing medication to specific patient subgroups based on genetic information.
 - c. Explain the role of pharmacogenetics in guiding decisions on advancing new drugs through the clinical trial pipeline.
2. Clinical Decision Making
 - a. Explain the concept of disease stratification and how this alters the marketing of medications.

- b. Describe opportunities for development of point-of-care medical decision analysis tools involving pharmacogenetic tests.
- 3. Clinical Systems
 - a. Describe the process whereby medications are developed, approved, and monitored for efficacy and side effects.
 - b. Explain how decisions are made by health care organizations and payers to include specific medications in formularies or for reimbursement, or the reimbursement for pharmacogenetic testing.
 - c. Describe the process whereby medications are developed, approved, and monitored for efficacy and side effects.

Competency 3: Informatics

Use knowledge of diverse sources of information to guide business decisions and recognize new business and career opportunities in personalized healthcare.

Learning Objectives

- 1. Sources of Information
 - a. Recognize the existing commercial and non-commercial sources of online and print healthcare information.
 - b. Demonstrate ability to access healthcare information, including statistics on utilization of healthcare services.
 - c. Recognize the sources of information related to the commercialization of products and services related to personalized healthcare (*e.g.*, patents, copyright, trademarks).
- 2. Storage and Sharing of Information
 - a. Appreciate the costs and benefits of development of systems for storage and sharing of health information.
- 3. Use of Information
 - a. Access data on healthcare utilization to guide business decisions.
 - b. Recognize the needs and opportunities to develop systems to deliver information to consumers and health professionals.
- 4. Legal, Ethical, and Regulatory Issues
 - a. Recognize the laws and ethical issues inherent in use and sharing of healthcare information.
 - b. Describe the process of education of consumers as part of the informed consent process.
 - c. Recognize the intellectual property laws related to development of new systems in health informatics.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to guide business decisions in a health care system or other form of business.

Learning Objectives

1. Social Roles
 - a. Explain how family relationships among employees contribute to genetics risk of disease and dissemination of information about that risk within the family.
 - b. Explain how social connectedness of an employee may influence response to disease risk or management.
 - c. Recognize the specific health risks that may occur in a particular work environment.
2. Social Status
 - a. Recognize that employees in an organization represent a range of socioeconomic status and that this may influence health status and access to care.
 - b. Describe the role of business in minimizing health care disparities based on racial, ethnic, and cultural factors.
3. Culture
 - a. Explain how different patterns of behavior in different cultural groups may influence health and risk of disease among employees in an organization.
4. Institutions
 - a. Describe the role of governmental laws, regulations, and financial resources in healthcare utilization by individuals within a work environment.
 - b. Explain the various options for insurance coverage available to employees in an organization.

Law Student

A law student should achieve all of the competencies described under “General Undergraduate,” and, in addition, the following:

Competency 1: Genetics and Genomics

Use knowledge of the basic principles of inheritance, structure and function of genes and the genome, and the concept of genetic variation to provide advice to individuals, for-profit and not-for-profit entities, and the government regarding healthcare issues.

Learning Objectives

1. Principles of Inheritance
 - a. Explain the legal rights and duties that are associated with communication of medical information within families.
 - b. Describe the liabilities associated with failure to recognize familial risks of disease.
2. Genetic Variation
 - a. Explain how DNA sequence variants can be used in identity analysis, recognizing major pitfalls in interpretation.
3. Genetic Testing
 - a. Describe the approach to identity testing by DNA analysis.
 - b. Recognize the potential for errors in the interpretation or application of genetic tests.
 - c. Explain the role of patent law in genetic testing.
 - d. Explain to clients the potential risks of genetic testing and the laws that protect from those risks.
4. Management of Genetic Disorders
 - a. Recognize the consequences of departure from standards of care in management of genetic disorders.

Competency 2: Pharmacogenetics and Pharmacogenomics

Use knowledge about individual variation in response to pharmaceutical agents to recognize opportunities, liabilities, and responsibilities associated with development and usage of medications and provide guidance to the public, health professionals, businesses, and policy-makers.

Learning Objectives

1. Pharmacology
 - a. Recognize that a person’s genetic makeup can influence drug efficacy and risk of side effects.
2. Clinical Decision Making
 - a. Describe the process whereby the standard of care is determined for clinical decision-making regarding use of pharmacogenetics in health care delivery.

- b. Explain how pharmacogenetic variation can contribute to the determination of probable cause of an adverse event involving pharmacological treatment.
3. Clinical Systems
 - a. Describe the process whereby medications are developed, approved, and monitored for efficacy and side effects.
 - b. Explain intellectual property and patent laws as they relate to the role of pharmacogenetic and pharmcogenetic testing in the development and marketing of pharmacological agents.

Competency 3: Informatics

Use diverse sources of information to provide legal guidance to consumers, health professionals, and others.

Learning Objectives

1. Sources of Information
 - a. Recognize the existing commercial and non-commercial sources of online and print healthcare information.
 - b. Demonstrate ability to access healthcare information, including information related to legal precedents and actions.
2. Storage and Sharing of Information
 - a. Appreciate the legal risks associated with storage and sharing of healthcare information.
3. Use of Information
 - a. Describe the standard of care related to use and sharing of healthcare information.
4. Legal, Ethical, and Regulatory Issues
 - a. Recognize the laws and ethical issues inherent in use and sharing of healthcare information.
 - b. Describe the process of obtaining informed consent.
 - c. Describe local and national laws related to privacy of health information and protection against discrimination based on genetic information.
 - d. Recognize the intellectual property laws related to development of new systems in health informatics.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to guide legal advice provided to individuals or institutions.

Learning Objectives

1. Social Roles
 - a. Explain the legal obligations regarding transmission of genetic health information within families and the obligations to maintain individual privacy.

- b. Explain the rights and responsibilities of individuals and employers regarding occupational health and safety.
- 2. Social Status
 - a. Recognize the possibility that socioeconomic status may affect an individual's to access healthcare.
 - b. Describe laws and legal remedies available to groups to minimize healthcare disparities.
- 3. Culture
 - a. Describe how cultural behavioral norms, values, and beliefs are reconciled with legal rights and obligations regarding access to healthcare.
- 4. Institutions
 - a. Describe the role of governmental laws and regulations in healthcare utilization by individuals.
 - b. Explain how health care is financed and rights and obligations of individuals and institutions in providing access to care.

Engineering and Computer Science Student

An engineering student should achieve all of the competencies described under “General Undergraduate,” and, in addition, the following:

Competency 1: Genetics and Genomics

Use knowledge of the basic principles of inheritance, structure and function of genes and the genome, and the concept of genetic variation to develop or improve systems involved in healthcare delivery.

Learning Objectives

1. Genetic Testing
 - a. Develop systems for genetic testing, integration of results into electronic health records, and decision support tools.

Competency 2: Pharmacogenetics and Pharmacogenomics

Use knowledge about individual variation and the role of genetic factors in response to pharmaceutical agents to help design more effective medications and systems to guide medical decision-making.

Learning Objectives

1. Pharmacology
 - a. Explain how knowledge of disease mechanisms can be used to develop new types of pharmaceutical agents.
2. Clinical Decision Making
 - a. Describe opportunities for development of point-of-care pharmacogenetic testing and medical decision analysis tools.
3. Clinical Systems
 - a. Describe opportunities for development of systems to monitor medication usage and incidence of adverse events.

Competency 3: Informatics

Develop systems for accession, storage, and use of healthcare information for educational, research and clinical use by professionals or the public.

Learning Objectives

1. Sources of Information
 - a. Recognize the existing commercial and non-commercial sources of online and print healthcare information.
 - b. Recognize opportunities to develop and utilize new technologies in dissemination of information used by consumers and health professionals.
2. Storage and Sharing of Information
 - a. Recognize opportunities to develop systems to facilitate the storage and sharing of health information by consumers and health professionals.
3. Use of Information

- a. Recognize opportunities to develop systems to facilitate the use of health information by consumers and health professionals.
- 4. Legal, Ethical, and Regulatory Issues
 - a. Recognize the laws and ethical issues inherent in use and sharing of healthcare information.
 - b. Recognize the intellectual property laws related to development of new systems in health informatics.

Competency 4: The Social and Cultural Environment

Use knowledge of the roles of social and cultural factors in human health and disease to design systems to improve individual health outcomes.

Learning Objectives

1. Social Roles
 - a. Explain how workplace systems and design can be used to minimize work-related health risks.
2. Social Status
 - a. Recognize that systems and devices that improve healthcare may not be equally available to individuals of different socioeconomic status and/or race.
3. Culture
 - a. Recognize that systems and devices that improve healthcare may be perceived or used differently as a function of cultural, ethnic, or religious background.
4. Institutions
 - a. Describe the role of governmental laws, regulations, and financial resources in utilization of healthcare resources and devices by individuals.
 - b. Explain how technological advances in health care are financed and the role of third party payers in access to health care, disease prevention, and disease management.
 - c. Explain the role of pharmaceutical and medical device companies in development and marketing of drugs and medical devices.
 - d. Explain the role of public and private funding sources in support of medical research.