A Genomic Medicine Policy Framework

The College of American Pathologists
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NHGRI Genomic Medicine V
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Pathology and Genomic Medicine

● CAP multi-year strategic planning process concluded
  ▪ Genomics essential to future of pathology
  ▪ Pathologists key for cancer genomics
    ▪ Tissue selection, integration with histopath & other pathology test results

● CAP genomic medicine initiatives
  ▪ Genomics education for pathologists
  ▪ Accreditation standards for NGS
  ▪ Proficiency testing program for NGS
Many requests to CAP from Congress and federal/regulatory agencies for comments on genomic medicine issues/policies/bills

No framework for responses

Reactive, not proactive, approach to genomic medicine advocacy

In 2012, initiated development of a genomic medicine policy framework to guide responses & move to proactive advocacy
Collaboration between
- Council on Government & Professional Affairs (CGPA)
- Personalized Healthcare Committee (PHC)

Identified major issue categories*

Divided writing by issue, covering topics:
- Background of issue
- Work by CAP and others to date
- Needs
- Recommendations

Unified sections into coherent document*

* Approval by both committees (final in Jan 2013)
CGPA-PHC Work Group Members

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- Michael Misialek, MD, FCAP
- Fay Shamanski, PhD, CAP Staff
CAP Genomic Medicine Policy Framework White Paper

- Introduction
- Overview of issues
- Principle Statement: Pathologists in Genomic Medicine
- 12 Issues
  - Background
  - Work to date
  - Needs
  - Recommendations
- Summary of recommendations
1. Pathologists’ Visibility in Genomic Medicine
2. Infrastructure and Resource Needs
3. Impact of Patents and Exclusive Licensing
4. Interoperability and Other Health Information Technology (HIT) Issues
Genomic Medicine Issues (2)

5. Federal Regulatory Oversight of Genomic Testing

6. Pathologists as Patient Consultants for Genomic Medicine

7. Payment for Genomic Testing, Interpretations and Consultations

8. Privacy, Ethical, Legal and Social Issues for Genomic Medicine

10. Genomics Education and Training for Pathologists

11. Education of Healthcare Providers and Patients on Role of Pathologists in Genomic Medicine

12. Coordinated Care Models and Genomic Medicine
CAP Genomic Medicine Policy Framework 2013

Provides a global perspective for the role of pathologists in genomic medicine

Discusses issues affecting incorporation of genomic testing into pathology practices

Makes recommendations to guide genomic medicine advocacy efforts for pathologists
Moving Forward

- Developing advocacy approaches to key issues
- Planning annual review of Policy Framework
Genomic Medicine Issues Overview

1. Pathologists' Visibility in Genomic Medicine
2. Infrastructure and Resource Needs
3. Impact of Patents and Exclusive Licensing
4. Interoperability and Other HIT Issues
5. Federal Regulatory Oversight of Genomic Testing
6. Pathologists as Patient Consultants for Genomic Medicine
7. Payment for Genomic Testing, Interpretations & Consultations
8. Privacy, Ethical, Legal and Social Issues
10. Genomics Education and Training for Pathologists
11. Education of Healthcare Providers and Patients on Role of Pathologists in Genomic Medicine
12. Coordinated Care Models & Genomic Medicine