The PNA Regulatory requirements

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Background to the Regulations –The Advisory Group

- In July 2009 following a Written Ministerial Statement, a regulatory Advisory Group drawn from interested parties was set up.
- Terms of reference - '*subject to Parliamentary approval of proposals in the Health Bill 2009, to consider and advise on, and to help the Department devise, regulations to implement a duty on NHS primary care trusts to develop and to publish pharmaceutical needs assessments and on subsequent regulations required to use such assessments as the basis for determining the provision of NHS pharmaceutical services*'

Advisory Group

- Chair – Paul Burns. Membership includes representatives from NHS Employers, PSNC, GPC of the BMA, BHTA and patient organisations. LGA and Which? receive papers.
- Advisory Group met 9 times in 2009.
- The draft regulations and guidance are a result of their work on the provision in Health Act 2009 to require PCTs to develop and to publish PNAs.
- Guidance sub-group set up and met twice – co-opted PCT commissioners, contract administrators and a PSNC regional representative.

Advisory Group papers

- Agendas, minutes and papers for the Group can be found on the Dept of Health website at:

  http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/PharmacyWhitePaper/RegulationsAdvisoryGroup/index.htm

Overview of regulatory proposals

- All subject to Parliamentary process
- The Regulations set out the “by when, how and what” of PNAs
- For example, the process, services and information each PNA must contain – e.g.:
  - The assessment of needs and future needs;
  - Information to be contained including maps
  - Publication dates for first and later PNAs;
  - When PCTs must make a new assessment;
  - Local consultation requirements.
- Expected completion date for PNAs – February 2011

So what are the Regulatory requirements?

- The assessment of pharmaceutical needs (draft Regulations 3A and 3G) includes
  - Pharmaceutical and appliances services, LPS and dispensing services
  - Population and demographics, localities, choice
- Information to be contained in the PNA (draft Schedule 3A) includes
  - Statement of services, improvements and better access, assessment of gaps and future needs and process
- Map (draft Regulation 3B(2) and Schedule A paragraph 8)

So what are the Regulatory requirements? (2)

- Consultation requirements/publication and timelines (draft Regulations 3F and 3C)
  - e.g. LRCs, LINks, patient and consumer groups, neighbouring interests, minimum 60 days period
  - Publish by February 2011 (proposed)
- Revised assessments and supplementary statements (draft Regulations 3C and 3D)
  - Required where changes relevant to market entry have occurred since PNA published unless disproportionate
  - Can issue factual supplementary update
- PCT re-organisations/boundary changes (draft Regulation 3E)

Consultation on draft PNA regulations

- Consultation began 1 December 2009.
- Listening Events January 2010
- Ended 28 February
- What's happened since then

So what have we learnt from the consultation?

- ***NB – based on PCC events in January 2010***
- *Consistency across PCTs – to strengthen pharmaceutical services, pharmaceutical need and how PCT areas are divided into localities. This might be done via supporting guidance.*
- *Appeal rights against PNAs not Judicial Review*
- *The right to request a review of the PNA could be added to the regulations.*
- *Increase minimum consultation period to 90 days.*
- *Adequate consultation locally – e.g. a proper process using a variety of ways such as listening events to promote better local understanding and informed responses.*

So what have we learnt from the consultation? (2)

- *The use of plain English and avoiding jargon.*
- *Strengthen guidance to provide clarity around which patient groups can be consulted,*
- *Include voluntary/third sector and NHS trusts outside the PCT's area*
- *Provision for re-consultation before publication could be covered in guidance.*
- *Feed back the consultation outcomes*
- *Template or model PNAs to assist PNA production*
- *Support to PCT managers responsible for the production of the PNA – e.g. via a national network.*
- *Core datasets and templates to collect this information would assist both PCTs and contractors.*

So what have we learnt from the consultation? (3)

- *Exempt applications, in particular 100 hour pharmacies, and their potential to apply to reduce core hours.*
- *Evidence the need for the provision of services during extended hours within PNAs*
- *PCT capacity and capability to produce robust PNAs.*
- *Ownership by the PCT Board crucial – the Board should sign off final PNA and that it complies with process and regulations.*
- *Add the PNA to the PCT's risk register to raise profile.*
- *Identification of gaps and pharmaceutical needs within the PNA could lead to a flurry of applications or raise expectations which the PCT can not then meet.*
- *Role of Strategic Health Authorities (SHAs) to sign PNAs off.*