

# **NATIONAL HEALTH SERVICE SCOTLAND ACT 1978**

## **THE CHILDHOOD IMMUNISATION SCHEME (DIRECTED ENHANCED SERVICES) (SCOTLAND) DIRECTIONS 2019**

The Scottish Ministers give the following Directions, in exercise of the powers conferred by sections 17E(3A), 17M, 105(6) and 105(7) of the National Health Service (Scotland) Act 1978(a), and all other powers enabling them to do so.

In accordance with section 17M(4) of the 1978 Act the Scottish Ministers have consulted with the bodies appearing to them to be representative of persons to whose remuneration these directions relate and with such other persons as they think appropriate.

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(a) 1978 c.29; Section 2(5) was amended by section 66(1) and Schedule 9, paragraph 19(1) of the National Health Service and Community Care Act 1990. Section 17E(3A) was inserted by section 2(4)(c) of the Primary Medical Services (Scotland) Act 2004. Section 17M was inserted by S.S.I. 2004/58. Section 105(7) was amended by Schedule 6, paragraphs 5(1)(a), 5(1)(c) and 5(1)(d) and Schedule 7 to the Health Services Act 1980 c.53, section 29(1) and Schedule 9, Part 1, paragraph 24 to the Health and Social Services and Social Security Adjudications Act 1983 c.41, and Schedule 4 paragraph 60 to the Health Act 1999.

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### PART 1

#### GENERAL

1. These Directions may be cited as the Childhood Immunisation Scheme (Directed Enhanced Services) (Scotland) Directions 2019 and come into force on 2 October 2019 but have effect from 1 April 2019.

#### Application

2. These Directions are given to Health Boards in Scotland and apply in relation to Scotland only.

3. These Directions relate to payments made by Health Boards to PMS contractors under a general medical services (“GMS”) contract, a section 17C agreement or a section 2C arrangement for Childhood Immunisation and Pre-school Booster Services.

#### Interpretation

4.—(1) In these Directions—

“the 1978 Act” means the National Health Service (Scotland) Act 1978;

“the 2006 Act” means the National Health Service Act 2006(a);

“the 2018 Regulations” means the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018(b);

“additional service” in relation to the inclusion of a vaccine, means the additional service as defined in the contract as applicable.

“APMS Contractor” means alternative provider medical services contractor, which is a contractor providing services under arrangements made under section 83(2) of the 2006 Act,

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(a) 2006 c. 41

(b) S.S.I.2018/94

section 41(2) of the NHS (Wales) Act 2006(a), section 2C(2) of the 1978 Act, or Article 56(2)(b) of the Health and Personal Social Services (Northern Ireland) Order 1972;

“booster courses” means the reinforcing doses for protection against diphtheria, tetanus, pertussis and poliomyelitis;

“CCG practice” means Clinical Commissioning Group practice which is a practice providing services under arrangements made under section 83(1) of the 2006 Act, section 41(1) of the National Health Service (Wales) Act 2006 or Article 56(2)(a) of the Health and Personal Social Services (Northern Ireland) Order 1972;

“Childhood Immunisation and Pre-school Booster additional service” means the provision of a PCV vaccine and the combined Hib/MenC vaccine which the PMS contractor has agreed to provide as an additional service under their PMS contract;

“Childhood Immunisation Scheme” is as defined in direction 5; “Childhood Immunisation Scheme Plan” has the meaning given in direction 7;

“Childhood Immunisation Scheme Register” has the meaning given in direction 7;

“CHI number” means community health index number;

“completed immunisation course” means an immunisation course for which the final completing vaccination has been administered;

“data cut-off date” is the date in the final month of a quarter, determined by a Health Board, after which it is not in a position to accept new data in respect of payments to be made at the end of that quarter. It is therefore the last date at which the Contractor may submit data to the Health Board if it is to receive payment in that quarter, and the Health Board’s cut-off date for data before they can calculate quarterly payments;

“exception reporting” is the reporting of persons who have declined vaccinations;

“the Green Book” means the guidance on vaccines and vaccination procedures which is published by Public Health England, as updated from time to time;

“HiB/Men C” means the HiB/Men C Booster vaccine;

“immunisation course” means the course of immunisations that are to be administered to prevent a particular condition or conditions for a given child of a given age and condition;

“increased risk children” has the meaning given in direction 30.

“NHS National Services Scotland” means the Common Services Agency constituted under section 10 of the 1978 Act;

“NHS provider” means—

- (i) the PMS contractor;
- (ii) another PMS contractor
- (iii) a PMS provider;
- (iv) an APMS contractor; or
- (v) a CCG practice;

“PMS contract” means a primary medical services contract, which is to be construed as a reference to the particular type of contract that is applicable to a primary services contractor; but it does not include a person with whom a Health Board is making or has made contractual arrangements for the provision of primary medical services to prisoners in prison;

“PMS contractor” means a primary medical services contractor, who is—

- (b) a GMS contractor, being a contractor who provides primary medical services under a general medical services contract under section 17J of the 1978 Act;
- (c) Section 17C provider, being a person with whom a Health Board has entered into arrangements under section 17C of the 1978 Act; or

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(a) 2006 c. 42

(d) a person with whom a Health Board has made arrangements for the provision of primary medical services under section 2C of the 1978 Act,

where references to a “contractor” are to be construed accordingly.

“PMS provider” means a PMS contractor, or another provider providing services under sections 83 or 84 of the 2006 Act, under section 41 or 42 of the National Health Service (Wales) Act 2006 under Articles 15B or Article 57 of the Health and Personal Social Services (Northern Ireland) Order 1972(a);

“PMS Regulations” means the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018(b);

“PCV” means the pneumococcal conjugate vaccine;

“month” means calendar month;

“quarter” means a quarter of the financial year;

“Quarterly TYOIP” means a Quarterly Two Year Olds Immunisation payment, in terms of direction 8;

“Quarterly FYOIP” means a Quarterly Five Year Olds Immunisation payment, in terms of direction 18;

“recommended immunisation courses” means the immunisation courses recommended by the guidance issued by the Chief Medical Officer for Scotland(c);

“recommended reinforcing doses” means the reinforcing doses recommended by the guidance issued by the Chief Medical Officer for Scotland(d);

“reinforcing doses” means vaccinations given subsequent to a primary course.

“routine childhood immunisation schedule” means the immunisation schedule detailed in Table 3 of Schedule 2 to these directions.

“SFE” means the Scottish Statement of Financial Entitlements, as updated from time to time;

“SIRS” means the Scottish Immunisation and Recall System;

“summary of product characteristics” or “SPC” in relation to a medicinal product has the meaning given in regulation 8 of the Human Medicines Regulations 2012(e);

(2) In the event of, and only to the extent of, any conflict between any term contained in these Directions or SFE, the following order of precedence applies—

- (a) any term in these Directions; and
- (b) the SFE.

(3) Unless the context otherwise requires—

- (a) other words and phrases used in these Directions have the same meaning as they do in the 1978 Act;
- (b) references to legislation (i.e. Acts and subordinate legislation) are to that legislation as amended, extended or applied, from time to time; and
- (c) words in the singular include the plural, and vice versa.

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(a) S.R. 1999/11

(b) S.S.I. 2018/67

(c) Guidance issued by the Chief Medical Officer for Scotland can be accessed on *Scottish Health on the Web*.

(d) Guidance issued by the Chief Medical Officer for Scotland can be accessed on *Scottish Health on the Web*.

(e) S.I. 2012/1916; Part 2 of Schedule 8 to the Human Medicines Regulations 2012 specified what a summary of Product Characteristics must contain.

## PART 2

### CHILDHOOD IMMUNISATION SCHEMES

#### **Basis of Childhood Immunisation Schemes**

5. Each Health Board must exercise its functions under section 2C of the 1978 Act of providing primary medical services within its area or securing their provision within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising for its area a Childhood Immunisation Scheme, the underlying purpose of which is to ensure that patients within its area—

- (a) who are two years of age but not yet three years of age are able to benefit from the recommended immunisation courses for protection against—
  - (i) diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenza type B (HiB);
  - (ii) measles, mumps and rubella; and
  - (iii) meningitis C;
- (b) who are five years of age but not yet six years of age are able to benefit from the recommended reinforcing doses for protection against diphtheria, tetanus, poliomyelitis and pertussis;
- (c) who meet the clinical criteria, are able to benefit from the PCV and HiB/MenC vaccinations;
- (d) who meet the clinical criteria, are able to benefit from the Rotavirus vaccinations.

(2) These Directions set out the conditions of payments to be made to PMS contractors under the scheme.

#### **Childhood Immunisation Scheme Contractors**

6.—(1) Before entering into any arrangements with a PMS contractor in accordance with these Directions, a Health Board must satisfy itself that the contractor with which it is proposing to enter into those arrangements—

- (a) is capable of meeting its obligations under those arrangements including under any plan agreed under those arrangements; and
- (b) in particular has the necessary facilities, equipment and properly trained and qualified general practitioners, other health care professionals and staff to carry out those obligations,

and nothing in these Directions is to be taken as requiring a Health Board to enter into such arrangement with a PMS contractor if it has not been able to satisfy itself in this way about that contractor.

(2) As part of arrangements made under these Directions, each Health Board must, each financial year, offer to enter into arrangements with each PMS contractor in its area, unless—

- (a) it already has such arrangements in place with the PMS contractor in respect of that financial year; or
- (b) the PMS contractor is not providing the childhood immunisations and preschool boosters additional service under its PMS contract (a).

#### **Childhood Immunisation Scheme Plans**

7.—(1) Health Boards and PMS contractors must, as part of their PMS contract, agree a Childhood Immunisation Scheme Plan. This plan must set out the arrangements that they have

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(a) This affords the contractor a reasonable opportunity to participate in the Scheme during that financial year.

entered into for the delivery of immunisations under directions 5(a) and (b). This will be the mechanism under which the payments provided for in these Directions will be payable, and it will cover the matters set out in direction 7(2).

(2) The Childhood Immunisation Scheme Plan must, in respect of each financial year to which the plan relates, include a requirement that the PMS contractor develops and maintains a Childhood Immunisation Scheme Register. This should register all the children for whom the PMS contractor has a contractual duty to provide Childhood Immunisation and Pre-school Booster Services. This may comprise electronically tagged entries in a wide computer database. PMS contractors may use the data held on SIRS or any equivalent system, when providing the information relevant to this requirement.

(3) Whilst the plan and register within this direction are principally in relation to immunisations under directions 5(a) and (b), these can also be used as guidance for delivery of immunisations under directions 5(c) and (d).

(4) The Health Board must vary the PMS contractor's contract so that the plan comprises part of the PMS contractor's contract and the requirements of the plan are conditions of the contract.

## PART 3

### QUARTERLY TWO YEAR OLDS IMMUNISATION PAYMENT

#### Conditions for Payment of Quarterly TYOIP

**8.**—(1) Health Boards must pay to a PMS contractor under its PMS contract a Quarterly TYOIP if—

- (a) the PMS contractor has, as part of its PMS contract, a Childhood Immunisation Scheme Plan which has been agreed with its Health Board;
- (b) the PMS contractor has met its obligations under its Childhood Immunisations Scheme plan;
- (c) the PMS contractor has made available to the Health Board—
  - (i) the number of children in cohort A (as defined in direction 9) by the date specified in Table 1 of Schedule 1;
  - (ii) the information specified in direction 11 of these Directions by the data cut-off date; and
  - (iii) any other information the Health Board reasonably requires to enable the Health Board to calculate that PMS contractor's Quarterly TYOIP.
- (d) as regards the cohort of children identified as cohort A under direction 9, subject to direction 10, by the end of that quarter —
  - (i) at least 70% for the lower payment; or
  - (ii) at least 90% for the higher payment;have completed the recommended immunisation courses for protection against the disease groups detailed in direction 5(a).

(2) All information supplied pursuant to or in accordance with this direction must be accurate.

(3) If the PMS contractor delays in providing the information the Health Board requires in terms of direction 8(1)(c) to calculate the Quarterly TYOIP beyond the data cut-off date, the amount is to fall due at the end of the next quarter.

(4) No Quarterly TYOIP is payable if the contractor provides the necessary information under direction 8(1)(c) more than four months after the final date for immunisations which could count towards the payment.

(5) If the contractor breaches any of the conditions detailed in this direction, the Health Board must withhold payment of all or part of a Quarterly TYOIP that would otherwise be payable.

(6) Notwithstanding direction 8(4), the Health Board may make payment of a Quarterly TYOIP despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;
- (c) a period of—
  - (i) maternity leave;
  - (ii) paternity leave;
  - (iii) adoption leave;
  - (iv) parental leave; or
  - (v) shared parental leave,

as determined by the period of entitlement of the said contractor;

- (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;
- (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;
- (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
- (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
- (h) any period during which the contractor has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.

(7) Contractors may use the data held on SIRS, or any equivalent system, when providing relevant information to Health Boards.

### **Terms relevant to Calculations**

**9.** For the purposes of calculations in this Part—

“A” is the number of two year olds PMS whom the contractor is under an obligation to include in their Childhood Immunisation Scheme Register on the first day of the quarter in respect of which the PMS contractor is seeking payment, and “cohort A” is taken to mean the group formed by the children who comprise A;

“B” is the number of completed immunisation courses needed to meet the 70% target;

“C” the number of completed immunisation courses needed to meet the 90% target;

“D” is the number of children in cohort A who, by the end of the quarter to which the calculation relates, have completed immunisation courses in the disease group detailed at direction 5(a)(i), and “cohort D” is taken to mean the group formed by the children who comprise D

“E” is the number of children in the cohort A who, by the end of the quarter to which the calculation relates, have completed immunisation courses in the disease group detailed at direction 5(a)(ii), and “cohort E” is taken to mean the group formed by the children who comprise E

“F” is the number of children in the cohort A who, by the end of the quarter to which the calculation relates, have completed immunisation courses in the disease group detailed at

direction 5(a)(iii), and “cohort F” is taken to mean the group formed by the children who comprise F

“G” is, in relation to the children on the PMS contractor’s Child Immunisation Scheme Register, the number of completed immunisation courses in the disease group detailed in direction 5(a)(i) which were completed before the end of the quarter to which the calculation relates, by an NHS provider;

“H” is, in relation to the children on the PMS contractor’s Child Immunisation Scheme Register, the number of completed immunisation courses in the disease group detailed in direction 5(a)(ii) which were completed before the end of the quarter to which the calculation relates, by an NHS provider;

“I” is, in relation to the children on the PMS contractor’s Child Immunisation Scheme Register, the number of completed immunisation courses in the disease group detailed in direction 5(a)(iii) which were completed before the end of the quarter to which the calculation relates, by an NHS provider;

“J” is the total number of completed immunisation courses that can be considered to count towards the contractor’s achievement of the targets; “K” is the number of completed immunisation courses in the disease group detailed in direction 5(a)(i) where the completing vaccination was carried out other than by an NHS provider. This can be calculated as D minus G.

“L” is the number of completed immunisation courses in the disease group detailed in direction 5(a)(ii) where the completing vaccination was carried out other than by an NHS provider. This can be calculated as E minus H. “M” is the number of completed immunisation courses in the disease group detailed in direction 5(a)(iii) where the completing vaccination was carried out other than by an NHS provider. This can be calculated as F minus I.

“N” is the maximum amount payable to a PMS contractor when the 70% target is achieved;

“O” is the maximum amount payable to a PMS contractor when the 90% target is achieved;

### **Establishing the Cohort**

**10.** In establishing whether the required percentage of the cohort A in direction 9 have completed the recommended immunisation courses referred to in direction 8(1)(d), the Health Board is not required to determine whether any of that cohort have received the HiB/Men C Booster, recommended in the provisions set out at Schedule 2 of these directions, for administration around 2 and 3 months. The administration of that HiB/Men C Booster vaccination or Rotavirus vaccination is not a requirement for payment under this part.

### **Information to be Supplied by the PMS Contractor**

**11.**—(1) The PMS contractor must provide to their Health Board the numbers D, E, F, G, H and I by the data cut-off date.

### **Calculation of Quarterly TYOIP**

**12.** Health Boards must determine the number of completed immunisation courses that are required over the three disease groups in direction 5(a) in order to meet targets B and C. To determine this, the Health Board must make the following calculations—

(a)  $0.7 * A * 4 = B$

(b)  $0.9 * A * 4 = C$  (a)

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(a) Each of these calculations includes a multiplication factor of 4 as these targets are each in respect of the 3 immunisations that are required for 2 year olds, one of which is given the value of 2.

**13.**—(1) Health Boards must calculate which, if any, target was achieved by the contractor. Only completed immunisation courses carried out by an NHS provider are to count towards the determination of whether or not the targets have been achieved. To determine this, the Health Board must make the following calculations—

(a) For the 70% target =  $(D * 2) + E + F$

(b) For the 90% target =  $(D * 2) + E + F$

(2) (a) If the result for the calculation at direction 13(1)(a) is greater than or equal to B, then the 70% target is achieved.

(b) If the result for the calculation at direction 13(1)(b) is greater than or equal to C, then the 90% target is achieved.

(3) For the purposes of the calculations in direction 13(1), no adjustment is to be made for exception reporting.

**14.**—(1) The Health Board must calculate the number of completed immunisation courses notified to them under direction 11 by the PMS contractor (by way of terms G, H and I) that can be considered to count towards that PMS contractor's personal achievement of the targets (J). To determine this, the Health Board must make the following calculation—

$$\begin{aligned} & (D * 2) - (K * 2) \\ + & (E) - (L) \\ + & (F) - (M) \\ = & J \end{aligned}$$

(2) In the case of the disease group detailed at direction 5(a)(i), if the value of  $(D * 2) - (K * 2)$  is greater than  $(A * 2) * 0.7$  or  $(A * 2) * 0.9$  (depending on which target is achieved), then it must be treated as the result of  $(A * 2) * 0.7$  or, as the case may be,  $(A * 2) * 0.9$ .

(3) If the values  $E - L$ , or  $F - M$  are greater than  $A * 0.7$  or  $A * 0.9$  (depending on which target is achieved), then they must be treated as the result of  $A * 0.7$  or, as the case may be,  $A * 0.9$ .

**15.** The maximum amounts payable to the PMS contractor for the 70% target (N) and 90% target (O) are to be calculated as follows—

(a)  $N = A/63 * £722.32(a)$

(b)  $O = A/63 * £2,166.97$

**16.** The Quarterly TYOIP payable by the Health Board to the PMS contractor can then be calculated as a proportion of the maximum amounts payable as follows—

(a) For the 70% target, the Quarterly TYOIP =  $N * J/B$

(b) For the 90% target, the Quarterly TYOIP =  $O * J/C$

### Payment of Quarterly TYOIP

**17.** The amount payable as a Quarterly TYOIP under direction 16 falls due to the PMS contractor on the last day of the following quarter. The timetable in accordance with which the TYOIPs will be made can be found in Table 1 of schedule 1 of these Directions.

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(a) The divisor 63 is used because the average number of two year olds per 5000 population in the United Kingdom is 63.

**PART 4**  
**QUARTERLY FIVE YEAR OLDS IMMUNISATION PAYMENT**

**Conditions for Payment of Quarterly FYOIP**

**18.**—(1) Health Boards must pay to a PMS contractor under its PMS contract a Quarterly FYOIP if—

- (a) the PMS contractor has, as part of its PMS contract, a Childhood Immunisation Scheme Plan which has been agreed with its Health Board;
- (b) the PMS contractor has met its obligations under its Childhood Immunisations Scheme plan;
- (c) the PMS contractor has made available to the Health Board—
  - (i) the number of children in cohort P (as defined in direction 19) by the date specified in Table 1 of Schedule 1;
  - (ii) the information specified in direction 20 of these Directions by the data cut-off date; and
  - (iii) any other information the Health Board reasonably requires to enable the Health Board to calculate that PMS contractor's Quarterly FYOIP.
- (d) as regards the cohort of children identified as cohort P under direction 19, by the end of that Quarter—
  - (i) at least 70% for the lower payment; or
  - (ii) at least 90% for the higher payment;

have received all the recommended reinforcing doses for protection against diphtheria, tetanus, pertussis and poliomyelitis.

(2) All information supplied pursuant to or in accordance with this direction must be accurate.

(3) If the PMS contractor delays providing the information the Health Board requires in terms of direction 18(1)(c) to calculate the Quarterly FYOIP beyond the data cut-off date, the amount is to fall due at the end of the next quarter.

(4) No Quarterly FYOIP is payable if the PMS contractor provides the necessary information under direction 20 more than four months after the final date for immunisations which could count towards the payment.

(5) If the PMS contractor breaches any of the conditions detailed in this direction, the Health Board will withhold payment of all or part of a Quarterly FYOIP that is otherwise payable.

(6) Notwithstanding direction 18(4), the Health Board can make payment of a Quarterly FYOIP despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;
- (c) a period of—
  - (i) maternity leave;
  - (ii) paternity leave;
  - (iii) adoption leave;
  - (iv) parental leave; or
  - (v) shared parental leave,

as determined by the period of entitlement of the said contractor;

- (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;

- (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;
- (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
- (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
- (h) any period during which the contractor has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.

(7) PMS contractors may use the data held on SIRS, or any equivalent system, when providing relevant information to Health Boards.

### **Terms relevant to calculations**

**19.** For the purposes of calculations in this Part—

“P” is the number of five year olds whom the Contractor is under an obligation to include in their Childhood Immunisation Scheme Register on the first day of the quarter in respect of which the PMS contractor is seeking payment, and “cohort P” is taken to mean the group formed by the children who comprise P;

“Q” is the number of completed booster courses needed to meet the 70% target;

“R” is the number of completed booster courses needed to meet the 90% target;

“S” is the number of children in the cohort P who, by the end of the quarter to which the calculation relates, have received the complete course of recommended reinforcing doses for protection against diphtheria, tetanus, pertussis and poliomyelitis, and “cohort S” is taken to mean the group formed by the children who comprise S;

“T” is the number of completed booster courses notified to the Health Board within cohort S that can be considered to count towards the PMS contractor’s achievement of the targets;

“U” is, in relation to the children on the PMS contractor’s Child Immunisation Scheme Register, the number of completed booster courses delivered to cohort S which were completed before the end of the quarter to which the calculation relates by a completing course administered by an NHS provider;

“V” is the maximum amount payable to a PMS contractor when the 70% target is achieved;

“W” is the maximum amount payable to a PMS contractor when the 90% target is achieved.

### **Information to be Supplied by the PMS Contractor**

**20.**—(1) In order to assist the Health Board in calculating the Quarterly FYOIP, the PMS contractor must provide to them the information represented in direction 19 by the letters S and U by the data cut-off date.

### **Calculation of Quarterly FYOIP**

**21.** Health Boards will first need to determine the number of completed booster courses that are required in order to meet either the 70% or 90% target. To determine this, the Health Board must make the following calculations—

(a)  $0.7 * P = Q$

(b)  $0.9 * P = R$

22.—(1) Health Boards will then need to determine which, if any, target was achieved. Only completed booster courses by an NHS provider are to count towards the determination of whether or not the targets are achieved. To determine this, the Health Board must make the following calculations—

- (a) if  $S$  is greater than or equal to  $Q$ , then the 70% target is achieved; and
- (b) if  $S$  is greater than or equal to  $R$ , then the 90% target is achieved.

(2) In terms of the calculations in paragraph (1), no adjustment is to be made for exception reporting.

23.—(1) The Health Board will then need to calculate the number of completed immunisation courses in cohort  $S$  that can be considered to count towards the PMS contractor's achievement of the targets ( $T$ ). To determine this, the Health Board must make the following calculation—

$$S - U = T$$

(2) If  $T > Q$  or  $R$  (depending on the target achieved) then  $T$  must be adjusted to equal the value of  $Q$  or  $R$  as appropriate.

24. The maximum amounts payable to the PMS contractor for the 70% target ( $V$ ) and 90% target ( $W$ ) are to be calculated as follows—

- (a)  $V = P / 58 * £223.73$  (a)
- (b)  $W = P / 58 * £671.21$

25. The Quarterly FYOIP payable to the PMS contractor can then be calculated as a proportion of the maximum amounts payable as follows—

- (a) For the 70% target, the Quarterly FYOIP =  $V * T / Q$
- (b) For the 90% target, the Quarterly FYOIP =  $W * T / R$

### **Payment of Quarterly FYOIP**

26. The amount payable as a Quarterly FYOIP under direction 25 falls due to the PMS contractor on the last day of the following quarter. The timetable in accordance with which the FYOIPs will be made can be found in Table 1 of Schedule 1 of these Directions.

## **PART 5**

### **PCV AND HiB/MEN C VACCINATIONS**

#### **Application and Interpretation**

27. Where reference is made to a vaccination being administered at or around a certain age, this is an indication of the recommended schedule for administration of the vaccine contained in the provisions as set out in Schedule 2 to these Directions. The specific timing of the administration of the vaccination, which must be within the parameters of the recommended schedule, is a matter for the clinical judgement of the relevant health care professional.

#### **Payment under the Routine Childhood Immunisation Schedule**

28.(1) Subject to direction 36, a PMS contractor qualifies for payment under this direction (“a qualifying PMS contractor”) in respect of each child on the contractor's Childhood Immunisation Scheme Register where—

- (a) that child has received, as part of their routine childhood immunisation schedule (see Table 3 of Schedule 2 for the full schedule)—

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(a) The divisor 58 is used because the average number of five-year-olds per population in the United Kingdom is 58.

- (i) three PCV vaccinations at 2 months, at 4 months and 13 months of age respectively,
  - (ii) one HiB/Men C at 12 or 13 months of age; and
- (b) in respect of whom the PMS contractor administered the final completing vaccination.
- (2) For the purposes of direction 28(b), the final completing vaccination means the third in the series of three PCV vaccinations which is scheduled to be administered at 12 or 13 months.
- (3) The Health Board must pay to a qualifying PMS contractor under this direction a payment of £15.02 for each child who has been vaccinated in accordance with this direction.

**Payment other than under the Routine Childhood Immunisation Schedule**

**29.** The Health Board must pay to a PMS contractor who satisfies the criteria under direction 33 a payment of £15.02 in respect of each child on the contractor’s Childhood Immunisation Scheme Register who has received the PCV vaccination in any of the circumstances set out in directions 30(5) to 32 and in respect of whom the contractor administered the final completing vaccination.

**Children at increased risk of pneumococcal infection**

**30.**—(1) For the purposes of this part—

- (a) an “increased risk child” is a child who has one or more risk factors identified by the Green Book as making a child at increased risk from infectious disease;
- (b) the “routine immunisation schedule” is found at Table 3 of Schedule 2; and
- (c) “presenting late” means that a child has presented before 12 months but cannot be vaccinated in accordance with the routine immunisation schedule.

(2) Where an increased risk child presents late for vaccination and—

- (a) consequently cannot receive, and has not received, the four vaccinations referred to in direction 28(1)(a) at the ages indicated there; but
- (b) who nevertheless still presents in time to enable them to receive, and did receive, two doses of PCV before the age of around 12 months, the HiB/MenC booster at around the age of 12 months and a third dose of PCV at around the age of 13 months;

the Health Board must pay to the PMS contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The third dose of PCV is considered the final completing vaccination for this purpose.

(3) Where an increased risk child who is over the age of around 12 months but under the age of 5 years presents late for vaccination (that is, not in accordance with the routine schedule set out in Table 3 of Schedule 2), and—

- (a) consequently cannot receive, and has not received, two doses of PCV before the age of around 12 months, the HiB/MenC booster at around the age of 12 months and a third dose of PCV at around the age of 13 months; but
- (b) who nevertheless receives either a single dose of PCV or, if they have asplenia, splenic dysfunction or, in are immunocompromised, two doses of PCV, the second of which is administered after the first dose;

the Health Board must pay to the PMS contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The single dose of PCV or, in the case of a child where a second dose of PCV is required, the second dose of PCV is considered the final completing vaccination for this purpose.

**Children who have had invasive pneumococcal disease**

**31.** Where a child who is over 13 months but under 5 years and who has previously had invasive pneumococcal disease receives a single dose of PCV in accordance with these Directions, the Health Board must pay to the PMS contractor administering the final completing

vaccination a payment of £15.02 in respect of that child, unless a payment is otherwise payable for that same final completing vaccination under direction 30(2) or direction 32(2). The single dose of PCV is considered the final completing vaccination for this purpose.

### **Children with an unknown or incomplete vaccination status**

**32.**—(1) Where a child who has an unknown or incomplete vaccination status receives vaccinations sufficient to ensure that they have received—

- (a) two doses of PCV before the age of 12 months,
- (b) the HiB/MenC booster at around the age of 12 months, and
- (c) a third dose of PCV at around the age of 12 or 13 months,

the Health Board must pay to the PMS contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The third dose of PCV is considered the final completing vaccination for this purpose.

(2) Where a child who has an unknown or incomplete vaccination status is too old to be vaccinated in line with the timescales under paragraph 1, but receives a single dose of PCV prior to the age of 24 months, the Health Board must pay to the PMS contractor who administers the final completing vaccination a payment of £15.02 in respect of that child. The single dose of PCV is considered the final completing vaccination for this purpose.

### **Eligibility for Payment**

**33.**—(1) A PMS contractor is only eligible for a payment under this Part if the following conditions are met—

- (a) the PMS contractor is contracted to provide the Childhood Immunisation and Pre-school Booster additional service;
- (b) the child in respect of whom payment is claimed was on the PMS contractor's Childhood Immunisation Scheme Register at the time the final completing vaccination was administered;
- (c) the PMS contractor administers the final completing vaccination to the child in respect of whom the payment is claimed;
- (d) subject to sub-paragraph (e) of this direction, the child in respect of whom the payment is claimed is aged around 13 months when the final completing vaccination is administered;
- (e) in the case of payments in respect of vaccinations administered in accordance with directions 30 or 31, the child must be under 5 years when the final completing vaccination is administered;
- (f) in the case of vaccinations administered in accordance with direction 32(2), the child must be under two years when the final completing vaccination is administered;
- (g) the contractor does not receive any payment from any other source in respect of any of the series of three PCV vaccinations and the HiB/MenC vaccination set out in Table 3 of Schedule 2 or in respect of any vaccination administered under any of the circumstances set out in directions 30 to 32 of this Part;
- (h) the PMS contractor submits the claim within 6 months of administering the final completing vaccination;
- (i) the PMS contractor must ensure that any health care professional who performs any clinical service in connection with the administration of the vaccine has such clinical experience and training as are necessary to enable them to properly perform such services;
- (j) that such health care professionals are trained in the recognition and initial treatment of anaphylaxis;

- (k) the PMS contractor must provide appropriate information and advice to the parent or carer of the child and, where appropriate, also to the child, about pneumococcal vaccinations and the HiB/MenC Booster vaccination; and
- (l) the PMS contractor must supply the Health Board with the information specified in direction 34 and record any information in accordance with that direction.,

### **Information and records**

**34.**—(1) The PMS contractor must supply the Health Board in respect of each child for which a payment is claimed the information listed at direction 34(2)(a)–(e) and in general, any information required under direction 34(2)(f).

(2) The information referred to in paragraph (1) is —

- (a) the name of the child;
- (b) the CHI number of the child;
- (c) subject to sub-paragraph (d), confirmation that the child has received three doses of PCV and one dose of HiB/MenC in accordance with Table 3 of Schedule 2;
- (d) if the claim is made in the circumstances set out in directions 30, 31 or 32, confirmation that all required vaccinations have been administered;
- (e) the date of the final completing vaccination, with confirmation that it has been administered by the PMS contractor; and
- (f) any information which the Health Board does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the contractor is eligible for payment under the provisions of this Part.

(3) The contractor must record in the child’s records—

- (a), kept in accordance with paragraph 68 of Schedule 6 of the 2018 Regulations or paragraph 36 of Schedule 1 of the PMS Regulations, any refusal of an offer of a pneumococcal vaccination or HiB/MenC Booster vaccination; and

(4) (b) where a pneumococcal vaccination or a HiB/MenC booster vaccination is administered, those matters set out in paragraph 5(2)(d) of Schedule 1 of the 2018 Regulations or paragraph 4(2)(d) of Schedule 3 of the PMS Regulations; The PMS contractor must make any returns required of it (whether computerised or otherwise) to the Practitioner Services Division (PSD) of the NHS National Services Scotland, and do so promptly and fully and ensure that all information provided pursuant to or in accordance with this direction is accurate.

(5) The Health Board may set aside the requirement under direction 33(1)(h) that the PMS contractor submit the claim within 6 months of administering the final completing vaccination despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;
- (c) a period of—
  - (i) maternity leave;
  - (ii) paternity leave;
  - (iii) adoption leave;
  - (iv) parental leave; or
  - (v) shared parental leave,

as determined by the period of entitlement of the said contractor;

- (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;
- (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;

- (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
- (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
- (h) any period during which the contractor has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.

(6) The PMS contractor is not entitled to payment of more than £15.02 in respect of a child under this Part, other than where—

- (a) the PMS contractor claims for payment for a final completing vaccination administered under the circumstances set out in direction 31; and
- (b) by virtue of that direction, the PMS contractor is entitled to payment under that paragraph, irrespective of any previous payment made in respect of that child under the provisions of this Part.

**35.**—(1) If the PMS contractor breaches any of the conditions in direction 33, the Health Board will withhold payment of all or part of the payment due under this section.

(2) Notwithstanding direction 35(1), the Health Board may make payment of all or part of the payment due under this section despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;
- (c) a period of—
  - (i) maternity leave;
  - (ii) paternity leave;
  - (iii) adoption leave;
  - (iv) parental leave; or
  - (v) shared parental leave,

as determined by the period of entitlement of the said contractor;

- (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;
- (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;
- (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
- (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
- (h) any period during which the contractor has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.

## **Claims for payment**

**36.** The PMS contractor is to submit claims in respect of the final completing vaccinations after they have been administered. The amount payable falls due to the PMS contractor on the last day of the following quarter.

**37.** Health Boards must ensure that the receipt and payment in respect of any claims are properly recorded and that each claim has a clear audit trail.

## **PART 6**

### **ROTAVIRUS (ROTARIX) VACCINE**

#### **Payment for Rotavirus vaccinations**

**38.**—(1) The Health Board must pay to a PMS contractor who qualifies for the payment in terms of direction 39, a payment of £7.67.

(2) A PMS contractor qualifies for payment under direction 39 in respect of each child registered with the contractor who has received, as part of their routine immunisation schedule, both the first dose of 1.5ml of Rotarix® vaccine at 2 months (approximately 8 weeks) of age and the second dose of 1.5ml at least 4 weeks after the first dose.

(3) Vaccinations given under direction 38(2) will be provided within the recommended timescale (SGHD/CMO/2013/4).

(4) For the purposes of this Part, the final completing vaccination is the second dose of 1.5ml of Rotarix administered at least 4 weeks after the first dose.

#### **Eligibility for Payment**

**39.** A PMS contractor is only eligible for payment under this Part where they meet the following conditions—

- (a) the child in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the final completing vaccination was administered;
- (b) the child in respect of whom the payment is claimed is under 24 weeks when the final completing vaccination is administered;
- (c) the PMS contractor must supply the Health Board with the information specified in direction 43 and record any information in accordance with that direction;
- (d) the PMS contractor must ensure that any health care professional who performs any clinical service in connection with administration of the vaccine
  - (i) has such clinical experience and training as are necessary to enable them to properly perform such services; and
  - (ii) is trained in the recognition and initial treatment of anaphylaxis;
- (e) the PMS contractor must provide appropriate information and advice to the parent or carer of the child, about rotavirus vaccinations; and
- (f) the contractor submits the claim within 6 months of administering the final completing vaccination.

**40.** The Health Board may set aside the requirement under direction 39(f) that the PMS contractor submit the claim within 6 months of administering the final completing vaccination despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;

- (c) a period of—
    - (i) maternity leave;
    - (ii) paternity leave;
    - (iii) adoption leave;
    - (iv) parental leave; or
    - (v) shared parental leave,
 as determined by the period of entitlement of the said contractor;
  - (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;
  - (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;
  - (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
  - (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
  - (h) any period during which the contractor has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.
- 41.** The Health Board must give a payment of £3.84 to a PMS contractor in respect of—
- (a) any child under this direction, where the PMS contractor has administered the first vaccination and the child does not attend for the second vaccination, and the contractor makes a claim 6 months after the first dose or at the end of the financial year; or
  - (b) where the PMS contractor only provides the final completing vaccination.

### **Claims for Payment**

**42.**—(1) The PMS contractor is to submit claims in respect of the final completing vaccinations after they have been administered. The amount payable falls due to the PMS contractor on the last day of the following quarter.

(2) The PMS contractor is to submit claims in respect of incomplete vaccination courses 6 months after the first dose was administered. The amount payable is to fall due quarterly on the last day of the quarter in which the claim has been submitted.

### **Information and Records**

**43.**—(1) The PMS contractor must supply the Health Board in respect of each child for which a payment is claimed the information listed at direction 43(2)(a)–(d) and in general, any information required under direction 43(2)(e).

(2) The information referred to in paragraph (1) is —

- (a) the name of the child;
- (b) the CHI number of the child
- (c) confirmation that the child has received two doses of Rotarix® vaccine in accordance with direction 38;
- (d) the date of the final completing vaccination, which must have been administered by the PMS contractor or their employed staff, or attached staff where this has been agreed with the Health Board; and

- (e) any information which the Health Board does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the PMS contractor is eligible for payment under the provisions of this Part.

(3) The PMS contractor must record in the child's records,

- (a) kept in accordance with paragraph 68 of Schedule 6 of the 2018 Regulations or paragraph 36 of Schedule 1 of the PMS Regulations, any refusal of an offer of a rotavirus vaccination; and
- (b) where a rotavirus vaccination is administered, those matters set out in paragraph 5(2)(d) of Schedule 1 of the 2018 Regulations or paragraph 4(2)(d) of Schedule 3 of the PMS Regulations.

(4) The PMS contractor must make any returns required of it (whether computerised or otherwise) to the Practitioner Services Division (PSD) of NHS National Services Scotland, and do so promptly and fully.

(5) All information provided pursuant to or in accordance with this paragraph must be accurate.

**44.**—(1) If the PMS contractor breaches any of the conditions in direction 39, the Health Board will withhold payment of all or part of the payment due under this section.

(2) Notwithstanding direction 44(1), the Health Board may make payment of all or part of the payment due under this section despite the delay, where the delay is caused by certain circumstances including (but not limited to) the following—

- (a) a period of annual leave, as determined by the period of annual leave entitlement of the said contractor;
- (b) a local or public holiday in Scotland;
- (c) a period of—
  - (i) maternity leave;
  - (ii) paternity leave;
  - (iii) adoption leave;
  - (iv) parental leave; or
  - (v) shared parental leave,

as determined by the period of entitlement of the said contractor;

- (d) a period of time when a contractor has been incapable of work due to sickness, injury or pregnancy;
- (e) a period of time of up to a maximum of 12 months, when a contractor is undertaking approved study or training;
- (f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983;
- (g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a contractor liable for compulsory whole-time service in those forces; or
- (h) any period during which the person has been suspended by a professional regulatory body, a Health Board or the Tribunal where that contractor was suspended after the contract with the Health Board was entered into.

## SCHEDULES

### SCHEDULE 1

Direction 17

#### Tables

**Table 1**

**Quarterly Timetable for TYOIP and FYOIP**

<i>Quarter in respect of which payment is made</i>	<i>Final date for immunisations which count towards the payment (last day of quarter)</i>	<i>Date the cohort of children is communicated to the Health Board by the PMS contractor(a)</i>	<i>Data cut-off date(b)</i>	<i>Date the payment from the Health Board falls due</i>	<i>Final date for submitting late returns to the Health Board (after which no payment can be received)</i>
First Quarter of the Financial Year	30th June	1st July	A date between 1 <sup>st</sup> and 30 <sup>th</sup> September set by the Health Board	30th September	31 <sup>st</sup> October
Second Quarter of the Financial Year	30th September	1st October	A date between 1 <sup>st</sup> and 31 <sup>st</sup> December set by the Health Board	31st December	31 <sup>st</sup> January
Third Quarter of the Financial Year	31st December	1st January	A date between 1 <sup>st</sup> and 31 <sup>st</sup> March set by the Health Board	31st March	30 <sup>th</sup> April
Fourth Quarter of the Financial Year	31st March	1st April	A date between 1 <sup>st</sup> and 30 <sup>th</sup> June set by the Health Board	30th June	30 <sup>th</sup> September

(a) In terms of Part 2 on TYOIP, this is cohort A (see direction 8(c)(i)) ; in terms of Part 3 on FYOIP, this is cohort P (see direction 18(c)(i)).

(b) Target dates for payment are on the basis that the Health Board receives the information they require by the required dates. If the contractor delays in providing the information the Health Board requires beyond the data cut-off date, then the amount payable will not fall due until the end of the next quarter.

## SCHEDULE 2

Direction 10

### Scottish Immunisation Programme – General Practice Elements

#### Part 1: Routine Childhood Immunisation Schedule

45. All children starting the immunisation programme at 2 months of age must follow the schedule below in Table 3, Vaccines to be delivered in GP practices.

##### *Pharmacy Issues*

46. Full details on the products are available in the Summary of Product Characteristics (SPC)(a).

**Table 3**

#### Vaccines to be delivered under these Directions

<i>When to immunise</i>	<i>Covered by these Directions</i>	<i>Incidentally covered</i>
Two months old	Diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b (DTaP/IPV/HiB)	Hepatitis B (HepB)
	Pneumococcal (PCV)	
	Rotavirus	
Three months old	Diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b (DTaP/IPV/HiB)	Hepatitis B (HepB)
	Meningitis C (Men C)	
	Rotavirus	
Four months old	Diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b (DTaP/IPV/HiB)	Hepatitis B (HepB)
	Pneumococcal (PCV)	
12-13 months	Haemophilus influenzae type b, Meningitis C (HiB/Men C)	
	Measles, mumps and rubella (MMR)	
	Pneumococcal (PCV)	
Three years four months to five years old	Diphtheria, tetanus, pertussis and polio (dTaP/IPV or DTaP/IPV)	

(a) "summary of product characteristics" or "SPC" in relation to a medicinal product has the meaning given in regulation 8 of the Human Medicines Regulations 2012 (S.I 2012/1916)